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(54) Portable device for sensing cardiac function and automatically delivering electrical therapy

Tragbare Vorrichtung zur Anzeige der Herzfunktion und zur automatischen Erzeugung
elektrotherapeutischer Impulse

Dispositif portatif de détection de fonction cardiaque et de délivrance automatique d'impulsions
électriques thérapeutiques

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(56) References cited:

EP-A- 0 128 103	EP-A- 0 199 218
FR-A- 2 091 400	GB-A- 1 467 344
US-A- 3 409 007	US-A- 3 826 245
US-A- 4 102 332	US-A- 4 102 346
US-A- 4 206 765	US-A- 4 576 170

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Description**FIELD OF THE INVENTION**

This invention relates to a patient-worn device according to the preamble of claim 1.

BACKGROUND OF THE INVENTION

A device according to the preamble of claim 1 is disclosed by the US-4,576,170. This known device to be worn externally by the patient uses a wire mesh, a skin adhering paint and tape strips to fix the electrode means on the patient's skin. During normal daily activities of the patient a reliable fixation of this device is hardly possible.

For several years, technology has been available for correcting excessively slow heart rates (bradycardia) by implantable devices, commonly referred to as pacemakers, which deliver microjoule electrical pulses to a slowly beating heart in order to speed the heart rate up to an acceptable level. Also, it is well known to deliver high energy shocks (180 to 360 joules) via external paddles applied to the chest wall in order to correct excessively fast heart rates and prevent the possible fatal outcome of ventricular fibrillation or certain ventricular tachycardias. Bradycardia, ventricular fibrillation and ventricular tachycardia are all electrical malfunctions (arrhythmias) of the heart and each may lead to death within minutes unless corrected by the appropriate electrical stimulation.

Because time delays in applying the corrective electrical treatment may result in death, implantable pacemakers and defibrillators have significantly improved the ability to treat these otherwise life threatening conditions. Being implanted within the patient, the device continuously monitors the patient's heart for treatable arrhythmias and when such is detected, the device applies corrective electrical pulses directly to the heart.

Pacemakers and defibrillators that apply corrective electrical pulses externally to the patient's chest wall also are used to correct such life-threatening arrhythmias but suffer from a drawback insofar as it may not be possible to apply the device in time during an acute arrhythmic emergency to save the patient's life. Such treatment is needed within a few minutes to be effective. Consequently, when a patient is deemed at high risk of death from such arrhythmias, the electrical devices are implanted so as to be readily available when treatment is needed. Alternatively, such patients are kept in a hospital where corrective electrical therapy is generally close at hand. Long term hospitalization, however, is frequently impractical due to its high cost or due to the requirements for patients to engage in normal daily activities.

There are also many patients susceptible to heart arrhythmias who are at temporary risk of sudden death. For example, patients undergoing a coronary artery

occlusion and myocardial infarction are at substantial risk of tachyarrhythmias for several weeks following the coronary artery occlusion. Such patients are generally hospitalized but could be discharged earlier if there was a practical means to protect them from life threatening arrhythmias. There are also numerous patients awaiting implantation of an automatic defibrillator who require an external defibrillator to be close at hand in case they experience a life-threatening tachyarrhythmia. Additionally, there are patients in need of an implantable defibrillator who are placed at inordinate risk due to the surgery required for implanting such a device.

It is evident from the above that there is a real need for providing an effective means whereby susceptible patients can be protected on a relatively long-term basis against the dangerous consequences of an electrical heart malfunction without having to undergo an implant procedure and without having to remain hospitalized.

SUMMARY OF THE INVENTION

It is an object of the invention to provide a system and means as referred to above, whereby a patient susceptible to certain heart arrhythmias can be effectively protected against harmful consequences resulting therefrom without having to undergo an implant procedure and without having to remain hospitalized.

Another object of the invention is to provide an effective form of externally applied electrical therapy which can provide relatively long-term protection to a patient against the consequences of heart arrhythmias without the patient having to forego normal everyday activities.

These objects are met by the characterising features of claim 1.

The present invention provides a system and means whereby susceptible patients may be substantially protected from arrhythmic death including a portable patient-worn external pacemaker/defibrillator that is comfortable to wear yet has the capability of continuously monitoring the patient for potentially lethal arrhythmias and delivering corrective electrical pulses quickly and appropriately in the event that such arrhythmia occurs. The invention also provides a supportive non-patient-worn system and means to optimize the operational readiness and reliability of the patient-worn device. Emphasis in the present inventive system and means is placed on optimizing reliable operation and further on maximizing patient compliance in wearing such a device by making the device comfortable and user compatible.

Further, according to the present invention, there are provided a number of means whereby the automatic external pacemaker/defibrillator may be worn comfortably by an at-risk patient. Included are means to minimize the weight of the device, means to distribute the weight-bearing surfaces over a large body area, means to allow the device to be loosely fitting in a standby mode, and means to allow a comfortable undergarment

to be generally positioned between the device and the patient's skin. Most importantly, the device also includes means to cause a low impedance pathway to be established for an electrical pulse to the heart when a potentially dangerous arrhythmia has been detected by the device.

Correct reliable positive detection of arrhythmias and minimal false detections are important to the utility of the wearable anti-arrhythmic device. Accordingly, it is also preferred that the device continuously monitor more than one physiological indicator of a treatable arrhythmia. Since various types of patient behavior may produce unreliable detection, means may be provided for advising the patient of the status of the detection circuits such that the patient may learn behavior patterns that optimize reliable device operation. The device may also include means whereby the patient may delay the delivery of a high energy shock if conscious, indicating that the arrhythmia is not yet life-threatening.

It is a further object of the invention to provide different types of system monitoring means to maximize safety, efficacy and reliability of the patient-worn device. Such monitoring means may include means to check operational readiness of the patient-worn device, means to check battery status of the device, means to recharge the batteries if necessary, means to record memory contents of the patient-worn device, and means to transmit vital data to remote health care personnel for problem solving and advising on correct device operation.

The above and other objects that will hereinafter appear, and the nature of the invention, will be more clearly understood by reference to the following description, the appended claims and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a block diagram of the functional elements of a first embodiment wearable automatic pacemaker/defibrillator device and maintenance subsystem for the wearable device;

Figure 2a is a diagrammatic sectional elevational view of a first embodiment combination ECG electrode/heart sound microphone used with the pacemaker/defibrillator device for heart beat detection; Figure 2b is an underneath plan view of the microphone;

Figure 3a is a plan view of a first embodiment sensing and pulsing electrode assembly used in the defibrillator device;

Figure 3b is a side elevational view of the electrode assembly;

Figure 3c is an end elevational view of the electrode assembly;

Figure 3d is an enlarged plan view, partly broken away, of the interior of the electrode assembly with the cover removed;

Figure 3e is an end elevational view of one of the

electrode components;

Figure 3f is a side elevational view of the electrode assembly with the cover removed;

Figure 3g is an underneath plan view of the electrode assembly with the cover partly removed;

Figure 3h is an exploded elevational view of parts of the electrode assembly;

Figure 4 is a diagrammatic in-use view of the first embodiment pacemaker/defibrillator as worn by a patient;

Figure 5a is a diagrammatic plan view of a respiration sensor as used in the first embodiment pacemaker/defibrillator device;

Figure 5b is a diagrammatic elevational view of the respiration sensor;

Figure 6 is a diagrammatic perspective view of the maintenance subsystem;

Figure 7 is a diagrammatic in-use view of a second embodiment pacemaker/defibrillator device in accordance with the invention, shown in association with an upper-body garment with which it is worn;

Figure 8 is a view of the second embodiment pacemaker/defibrillator device in its in-use position, and shown in somewhat more detail;

Figures 9a and 9b are sectional plan and sectional elevational views respectively of a sensing electrode assembly used in the second embodiment device;

Figures 10a and 10b are sectional elevational views of a pulsing electrode assembly used in the second embodiment device, Figure 10a showing the assembly in a holding mode, and Figure 10b showing the assembly in an operational mode;

Figures 10c, 10d and 10e are enlarged sectional elevational views of parts of the pulsing electrode assembly when in the holding mode.

Figures 11a, 11b and 11c show respective parts of the puncture mechanism in the operational mode;

Figures 11d, 11e and 11f show the respective parts in the holding mode;

Figure 12 is an underneath plan view of the pulsing electrode assembly;

Figures 13a and 13b are respective plan views of a voltage controlled heat operated release mechanism, Figure 13a being shown in the holding mode and Figure 13b being shown in the operation mode;

Figure 14 is a diagrammatic in-use view of a third embodiment pacemaker/defibrillator as worn by a patient;

Figures 15a and 15b are respectively a plan view and an end view of an electrode housing with a gas source remotely mounted;

Figures 15c and 15d are respective bottom views of the electrode housing, with a fluid container, resistive heating element and retaining member being shown with channels being removed in Figure 15c and being in place in Figure 15d;

Figures 16a and 16b are respectively a plan view

and an end view of the electrode housing with a gas source locally mounted within the pad housing; and Figure 16c is an enlarged end view showing increased detail of the electrode housing, including a fluid container, resistive heating element and retaining membrane.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Generally stated, in a preferred form of the invention as illustrated in the drawings, there is provided a patient-wearable automatic electric heart therapy device, such as device 10, shown in overall view in Figure 4, or device 200 shown in overall view in Figures 7 and 8, and a maintenance subsystem or module 12, shown in overall view in Figure 6 on which the respective therapy device 10 or 200 can be mounted when not in use on a patient, effectively to service, program and charge the device.

As shown in Figure 4, in a first embodiment, the patient-worn device may include a waist-encompassing belt 14 of suitable fabric, webbing or the like, which may be elasticized, or may incorporate sprung elements the belt having a low-profile connector or buckle 16, and a shoulder strap 18 of like material connected between front and rear portions of the belt. First and second like sensing and pulse electrode assemblies 20 are carried respectively on belt 14 and shoulder strap 18. Belt 14 also carries a pulse generator 24 which may have a supporting strap connection 26 with strap 18 and electrical conductors, diagrammatically indicated at 28 and 30, for receiving electrical signals from and delivering electrical pulses to the respective electrode assemblies 20. Assemblies 20 have respective sensing electrodes 22 and pulse electrodes 32.

In use of the device as thus far described, assemblies 20 are held in comfortable contact with a patient's chest wall and continuously monitor and detect the heart rhythm by means of the respective sensing electrodes 22. Alternatively, sensing electrodes may be traditional disposable E.C.G. electrodes placed on the patient's skin in a location separate from the pulse electrodes 32. In the event that the sensing electrodes detect a treatable heart arrhythmia, the electrodes will send the sensed signal via conductors 28 and 30 to the pulse generator, and in response thereto, the pulse generator will return appropriate treatment pulses to the respective pulse electrodes 32. Moreover, each of the electrode assemblies further includes means (to be described below) for automatically reducing the impedance of electrical transmission to the heart upon receipt of the appropriate treatment commencing signal from the pulse generator. Such impedance reducing means may include, for example, means for automatically tightening the respective pulsing electrodes 32 against the patient's skin, and means for automatically releasing an electrolytic electrode gel to the electrode-skin interface.

Reverting to Figure 4, it is seen that device 10 may

be worn over a comfortable undergarment 34, such as a T-shirt, which may have apertures 36 that receive the respective electrode assemblies 20. Attachments 38, such as patches of loop and pile Velcro-type fabric, may be provided between belt 14, strap 18 and the undergarment.

Figures 2a and 2b illustrate details of the respective sensing electrodes 22. Each sensing electrode, which is centrally located in its respective assembly 20, comprises a plastic, cylindrical housing 40 containing a telescoping inner chamber 42 which carries an ECG electrode 44, an associated amplifier 46, and an audio transducer or microphone 48. The ECG electrode 44 may be capacitive, conductive carbon, or any other design which permits long-term use without skin irritation. The microphone is acoustically coupled to a port 50 which conducts audio-frequency energy to the microphone diaphragm. The diameter of the inner chamber is typically about 2.5 cm. Installed over the amplifier 46 and microphone 48, and electrically connected thereto, is a flexible printed circuit 52 supplying power to and receiving signals from the amplifier and microphone. It is understood that the printed circuits of the respective electrodes are connected to the pulse generator 24 through conductors 28 and 30 referred to in connection with Figure 4.

The inner chamber 42 telescopes within the outer chamber 40 and a synthetic expanded foam pad 54 located beneath a chamber cover 60 applies pressure to the top of the inner chamber and thus to the skin surface, insuring constant contact between the ECG electrode surface and the skin whenever the system is worn.

Figures 3a-3c illustrate the overall outer appearance and dimensions of the respective electrode assemblies 20, showing the placement of the sensing electrode 22 within the pulse electrode 32. The electrode assemblies each have an outer housing 56 of a flexible, composite material having a skin contact area of approximately 100 square centimeters.

Figures 3d-3g illustrate the interior of the respective electrode assemblies with the housing removed. The respective sensing electrode 22 fits centrally within the respective pulse electrode and has a recess 58 provided in the top surface of the central chamber cover 60. Recess 58 contains an electrically-operated release or trigger mechanism, consisting of a heating coil of resistance wire 62 wound around a synthetic fiber activator member 64. Member 64 has headed ends 65 which attach to and retain two spring-loaded equalizer bars 68 and allowing springs 68 to exert force upon the bars which travel within two cantilevered tubes 70. Contained within tube 70 are synthetic fiber tension members 72, fastened at their ends to washers 74 and at their other ends, not shown, into the structure of belt 14 or strap 18 as the case may be. Thus, as the equalizer bars travel within the tubes, the tension members 72, by virtue of their attachment to the washers, are pulled through the tubes, applying tension to the ends of the belt 14 or strap 18 to which the respective electrode housing fas-

tens, thereby tightening the electrode assembly against the patient's skin and providing a firm form of impedance reducing means.

Between the tubes 70 at each side of the electrode body, and attached to grooves in central housing 40, are opposite capsules 76 containing a conductive fluid such as an electrolyte gel. Central portions of the equalizer bars 66 surround the gel capsules such that when activated, the bars move along and compress the capsules and extrude the gel toward the ends of the electrode assembly away from central housing 40. Elongated ports 82 at the outer ends of the capsules 76 communicate with channels 80 in a base member 84 of the electrode body. Figure 3g is a bottom view of the electrode assembly illustrating the gel channels 80 radiating from the capsule ports 82, and Figure 3h is an illustration of the cross section of the skin-contacting surface. The gel channels are open along their length but base member 84 is covered by a restrictor plate 86 with restricted openings 88 which communicate with the respective channels.

The dimension of the gel channels are such that there is little impedance to the flow of conductive gel over the length of the channels, but the openings 88 impede the gel flow somewhat. This differential flow resistance ensures that upon activation of the extruder mechanism, the conductive gel rapidly fills all of the channels and then slowly the gel will be extruded through the holes in the restrictor plate. After passing through the plate, the gel then infiltrates a metallic mesh or perforated foil pulse electrode plate 90, which carries the current necessary for the electrical treatment, whether it be pacing, cardioverting or defibrillating. As the gel wets the metallic member, the electrical connection to the skin is enhanced by significantly lowering the impedance at the interface and providing a second form of impedance reducing means.

In the dry, non-activated state, a comfortably soft and absorbent fabric 92 covers plate 90 and contacts the patient's skin. This fabric typically is cotton. The fabric may be sewn through the surface of the electrode or may be loosely fitted onto the electrode with edges that curl over the electrode's edge and are held taut by an elastic member. This latter configuration allows frequent exchanges of the fabric surface for cleanliness purposes.

Figures 5a and 5b illustrate a belt mechanism 94 which may be used to sense respiration movement. A strain gauge 96 is bonded to a metallic backing plate 98 which is attached firmly to belt 14. A protective molded cover 100 is applied over the gauge element which also encapsulates lead wires 102.

System operation will now be described with particular reference to Figure 1.

A set of sensors (monitoring means) is used to gather information as to the patient's condition. The monitoring means include the respiration sensor 94, previously described, for detecting chest wall movement, the microphone 48 for picking up heart or respiration sounds, the ECG electrodes 22 to monitor the surface electrocardiogram and a reference ECG electrode 106 (known per se) to establish a "common" potential for electrodes 22. The signals from the sensors are amplified and conditioned by respective amplifiers 108, 110, 112 and a signal processing network 114. The conditioned signals are applied to a microprocessor 116.

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The microprocessor, in conjunction with a system memory 118, performs all functions necessary for patient monitoring, time keeping and background operation, recording of arrhythmias and system events, communication with the maintenance subsystem 12, control of treatment sequences, self checks of system and electrode functioning, and monitoring of status switches 120 and 122. The microprocessor and memory together constitute essential elements of the pulse generator 24 described in connection with Figure 4. These items are well known per se in heart treatment equipment and will not be described in further detail.

Also contained in the system memory 118, are tests and conditions for declaring a treatable event. When a treatable event is sensed, the microprocessor will initiate treatment as programmed in the system memory. Treatment modes and sequences may be individually personalized for each patient and may include low or high energy cardioversion/defibrillation, and a wide range of pacing modalities.

When a treatable event is sensed, the microprocessor activates the pressure means 124 (namely, the release mechanism 62 previously described) which pulls the pulsing electrodes 32 tightly against the patient's chest wall. Simultaneously, the electrode gel 126 is released by the treatment electrode as previously described to produce a low resistance contact. An impedance sensing circuit 128 is incorporated in the system to verify that the low resistance condition exists. At this point, the microprocessor may issue a spoken warning to stand clear via a voice synthesizer 130 and speakers 132, and causes treatment to begin through the pulsing electrodes, either pacing by a pacing circuit 134 or high energy shock by a defibrillator circuit 136. The patient, at his or her option, may delay treatment by simultaneously depressing two "live man" switches 120. If the patient subsequently loses consciousness and releases the switches, treatment will begin; otherwise, the treatment is delayed.

Other functions which may be included in the system are an RF communications link to the maintenance system via receiver/transmitter 140 and antenna 142, and a power supply 144 which may have a rechargeable battery pack 146 to be charged by plugging into a charging port 148 on the maintenance system. An "on patient" sensor (switch 122) may be provided to inform the microprocessor that the device is in place on a patient. A self test feature may also be incorporated. Thus, by depressing one of the "live man" switches, the patient may initiate a test program which will report device status and/or any fault condition via speaker 132.

The maintenance subsystem 12, a block diagram of which is shown on the right hand side of Figure 1, may comprise a microprocessor-based support device for the belt device 10. The main functions of the maintenance subsystem are to provide a charger 150 for the belt power supply 144 and a communications link, for example between the belt and a telephone line. The charging may be effected either when the belt is on the maintenance device 12 using a built-in charging coil 152, or this coil may be extensible for remote use while the patient is wearing the belt. Alternatively, charging may be effected by alternating two battery packs. Communication with the belt is through an RF link 159 and an antenna 158. Communication with a telephone line is through a telephone dialer and modem 159 and a built-in speaker phone 160.

Other possible functions of the maintenance system will also be described. Thus, in Figure 1, reference 162 is a microprocessor and system memory. The microprocessor controls all system functions. It also serves as the system clock with a time and status display 164. The system memory preferably is large compared with the belt memory, allowing it to store more of the patient's electrocardiogram and other data. The belt memory may be periodically "dumped" into the maintenance system for storage and eventual relay to a physician via telephone.

The maintenance system may also serve as a test system for the belt. For this purpose, test electrode outputs 166 (Figure 6) may be located, such that when the belt is on the maintenance system, as determined by a sensor 168, the ECG test electrodes are in proximity to the belt pickup electrodes. Similarly, a respirator transducer 170 and a microphone test transducer 154 may be located near their corresponding sensors. This allows a full functional check of the belt sensing and detection mechanisms using test circuitry 162 (Figure 1). This testing can be done automatically or initiated by the patient using a test button 174.

The maintenance system may be powered by an AC line and may incorporate a back-up battery 176 in case of a power outage. Other features may include power and charging status lights 178, a single button 180 for emergency dialing of a physician, allowing diagnosis and treatment by telephone during an emergency, and a built-in speaker phone 182 for convenience. A compartment 184 may be provided for charging coil storage.

The monitoring means may be adapted for detecting QRS electrical depolarization of the patient's heart and the patient's rate may be determined from the interval between QRS detections. Additionally, the rate of change of the patient's heart rate may be monitored. Also, or alternatively, the presence of an aortic valve closure sound may be used to verify or substitute for the sensing of a QRS electrical complex. A treatable tachycardia may be declared when the patient's heart rate exceeds a preset value for a preset time duration and the heart rate of change exceeds a preset level. A treat-

able bradycardia may be declared when the patient's heart rate drops below a preset rate for a preset time duration. Further, gasping motion or respiration may be used as a detection parameter for delivering a high-energy defibrillating shocks and may be used in combination with fast heart rate and/or fast heart rate acceleration for indicating the need for delivering of a high-energy defibrillating shock.

As shown in Figures 7 and 8, a second embodiment 10 heart therapy device 200, of similar functioning to the first embodiment device 10, may be worn with a comfortable, vest-like upper body garment structure 202, which may be form fitting and elasticized to ensure adequate contact of the sensing transducer with the skin surface, as will be described. The vest is constructed with sewn-in pockets 204 equipped with slide fasteners 206 or other positive-acting closures, into which electrode assemblies 208 of the device 200 are inserted prior to patient use, with pulse generator 210 of the device suitably attached to the vest and a conductor system 212 extending between the respective electrode assemblies and the pulse generator. It is understood that device 200 may be in the form of a self-contained treatment package with the conductors being contained in a suitable sheath 214 or the like which connects the various subassemblies. The device may also include a respiration sensor. The arrangement permits multiple vest to be hand for cleanliness purposes, and allows the treatment package to be rapidly and easily changed between vests, ensuring relatively uninterrupted sensing and treatment.

The vest may additionally be fitted with appropriately located reinforcement sections, which upon receipt of a treatment-commencing signal from the pulse generator, translates movement of an upper half of the respective electrode housing into radial pressure against the patient's skin. As in the previous embodiment the vest may have apertures allowing the respective electrode assemblies to contact the patient's skin. Additionally, the vest may have attachment means along its lower edge for attaching same to a belt, a lower body garment, or the like.

Each of the two ECG sensing/pulse delivery electrode assemblies 208 includes an ECG sensing electrode 218 (Figure 9b) located within a plastic cylindrical housing 220, which is centrally located within the respective assembly 208. Electrode housing 220 contains the flexible, conductor-fiber-filled sensing electrode 218, two motion-detecting elements 222, 224, and associated amplifiers 226. The sensing electrode 218 is free to move vertically within the housing, but is limited in travel by molded-in bosses 228, 230. A spring 232 located beneath the chamber cover applies pressure to the top of the sensing electrode and thus to the patient's skin surface, ensuring constant contact between the ECG electrode surface and the skin whenever the system is worn.

Each electrode assembly 208 additionally consists of a top plate 234 (see Figures 10a-10c), a housing

cover 236, a compression plate 238, two U-shaped fluid container chambers 240, two conductive fluid-containing sacs or pouches 242, a compression spring 244, two puncture mechanisms 246, and a voltage controlled, heat operated release mechanism, to be described.

The chambers are permanently fastened to the housing cover with fold-over tabs 248. The compression plate 238 is installed beneath the housing cover 236, and between the compression plate and the bottoms of the chambers are situated the flexible sacs or pouches 242 containing the electrolyte or like conductive fluid.

The plates 234 and 238 are held in close proximity by a heat operated release mechanism, consisting of a cylindrical release sleeve 262, a torsion spring 264 located in a peripheral groove 278 at the upper end of the release sleeve, a resistance wire heating element 266, and a synthetic fiber restraining member 268 (see Figures 13a, 13b). Member 268 is fastened at one end to a pierced tab 270, or like fastener formed in top plate 234, and at the other end to a deformed zone in the torsion spring 272. An insulating strip 274 is installed under the heating element to isolate it from the top plate and to provide a means to make electrical connections to the element.

A flange 276 on the lower end of the release sleeve engages the underside of the compression plate 238 and the groove 278 on the upper end of the sleeve engages the torsion spring 264. The spring, (when compressed), engages the upper side of the top plate.

Upon receipt of the appropriate signal from the pulse generator 210, upon detection of a treatable heart condition, the heating element 266 melts through the restraining member 268, releasing the free end of the torsion spring 264, which disengages from the groove in the release sleeve, freeing the top plate.

The compression spring 244, applies pressure against the top plate 234, causing it to move upward, (away from the skin), and carry with it the top half of the electrode housing 260, to which it is fastened. This movement, via the enclosed pockets 204 in the vest structure, and the reinforcements sewn within the vest, transmits radial pressure against the chest wall, reducing the impedance at the electrode/skin interface, and ensuring adequate pressure for effective pulse delivery.

Additionally, the compression spring 244 applies downward pressure upon the compression plate 238 and the release sleeve 262, which are free to move toward the skin. This downward pressure is transmitted to the fluid sacs 242. The puncture mechanisms include pointed members 250 attached to the compression plate, which move through respective retaining tubes 252 and puncture the bottom surfaces of the fluid containers, when plates 234 and 238 are forced apart. As the compression plate moves through its travel, the fluid medium is forced out of the sacs into ports 256 and channels 254 situated in a bottom part of the electrode assembly, and by these means are transmitted to the pulsing electrode 258 and to the patient's skin surface, saturating this interface, and reducing the impedance

thereby.

It will be apparent that electrode structures similar to structures 208 can also be employed in a harness-type garment which may include a belt, such as belt 14 and/or a shoulder strap, such as strap 18 as previously described.

In still another form of the invention, the impedance reducing mechanism may include a fluid-pressure actuated mechanism for increasing pressure of a pulse electrode against the patient's skin in response to a treatable heart condition being detected. Such fluid pressure actuated mechanism may include a gas cartridge for tightening an electrode-carrying belt or strap such as belt 14 or strap 18 previously described.

One such embodiment consists of a gas source, (pressurized cylinder) 310, Figure 14, and an electrically-operated actuator, or squib, 312, located on or near the pulse generator package 210, with conduits 314, for carrying gas under pressure to each electrode housing 316, upon activation of the gas source.

A second such embodiment consists of a local gas source 318, and actuator 320, located in each electrode housing, as shown in Figures 16b and 16c.

In both such embodiments, each electrode may have an inflatable cell or bladder 322, (Figures 15 and 16) which at activation expands, supplying movement in two directions.

At detection, an electrical signal is sent to the gas actuator, releasing the gas from the respective gas source and pressurizing the inflatable cell.

A resistive heater 234, held in proximity to the lower wall 326, of the fluid sac 328, by a thermally bonded membrane 330, or other attachment means, heats when activated, melting through the wall of the sac and the membrane, thereby releasing electrolyte fluid or gel from the sac.

Pressure supplied by the inflated cell squeezes the fluid out of the sac and into ports 332, and channels 334, as in the previous embodiments saturating the skin contacting treatment electrode 336, and the skin surface.

The movement of the cell by expansion is simultaneously transmitted to the upper housing half 338, of the electrode assembly causing it to move upward, away from the skin. This movement, via an enclosed pocket 204 in the vest structure, and the reinforcements sewn within the vest or garment, transmits radial pressure against the chest wall, reducing the impedance at the electrode/skin interface.

The monitoring base station may be equipped with a known volumetrically controlled source of gas that can check the integrity of the inflatable cell or bladder by verifying the maintenance of pressure subsequent to test gas inflation by the monitoring system.

The vest/harness structure is designed to provide sufficient slack space to permit long term wearing comfort. The structure is initially fitted prior to day-to-day wear to ensure that this slack space is restricted to a dimension less than the combined electrode expansion

distances, ensuring adequate pressure for effective pulse delivery.

While only preferred embodiments of the invention have been described herein and in detail, the invention is not limited thereby and modifications can be made within the scope of the attached claims. 5

Claims

1. A patient-worn device for automatically delivering electrical therapy to the heart upon the occurrence of a treatable heart arrhythmia, the device comprising: monitoring means (20, 22) for continuously sensing the patient's heart status, skin-contacting treatment electrode means (32), a source of electrical energy (24) for supplying electrical pulses to the electrode means (32), discrimination means for receiving signals from the monitoring means (20, 22) and determining the presence of a treatable heart arrhythmia, and switching means actuated by the discrimination means responsive to the detection of a treatable arrhythmia for connecting the source of electrical energy (24) to the electrode means (32) and applying appropriate electrical pulses to the heart, said patient-worn device being characterized by
10 impedance reducing means actuated by the discrimination means responsive to the detection of a treatable heart arrhythmia for automatically reducing the impedance to electrical current flow at an interface between the electrode means (32) and the patient's skin.
2. The device as defined in claim 1 wherein the electrode means (32) is carried on carrier means (202) in the form of an upper body harness or garment and the impedance reducing means includes means for tightening the carrier means (202) thereby pressing the electrode means (32) against the skin. 15
3. The device as defined in claim 1 which includes a source (242) of electrically conductive fluid material (126) and wherein impedance reducing means includes means for releasing the electrically conductive material from said source (242) and delivering same to the interface between the electrode means (32) and the patient's skin. 20
4. The device as defined in claim 1 wherein the device (10) is in the form of a body harness which includes a chest-encompassing belt (14) and an over-the-shoulder strap (18), wherein the monitoring means (20, 22) includes at least one monitor on each of said belt (14) and said strap (18), and wherein the electrode means (32) includes at least one pulsing electrode on each of said belt (14) and said strap (18). 25
5. The device as defined in claim 4 in combination with an undergarment (34) over which the device (10) is to be worn, the undergarment including apertures (36) for the monitors (22) and electrodes (32). 30
6. The device as defined in claim 4 wherein the harness comprises elastic means and is length-adjustable to exert a controlled compression force against the body by the monitoring means (20, 22) sufficient to acquire reliable electrocardiographic signals. 35
7. The device as defined in claim 4 wherein the chest belt (14) includes means for measuring chest movement of respiration. 40
8. The device as defined in claim 1 wherein the device comprises a harness or vest (202), a subassembly including the electrode means (32), the discrimination means and conductor means connecting the electrode means (32) with the discrimination means, and means (204, 206) for releasably securing the subassembly on the harness or vest (202). 45
9. The device as defined in claim 8 wherein the means (204, 206) for releasably securing the subassembly on the vest (202) includes pocket means (204) in the vest (202) for receiving and retaining the electrode means (32, 218). 50
10. The device as defined in claim 9 wherein the impedance reducing means includes means (232) for expanding the electrode means (218) within the pocket means (204) and thereby applying the electrode means (218) with increased pressure against the patient's skin. 55
11. The device as defined in claim 1 which includes signal generating means (130, 132) actuated by the discrimination means responsive to detection of a treatable arrhythmia for warning the patient, and a patient-activated switch means (120) for delaying the connection of the energy source to the electrode means (32). 60
12. The device as defined in claim 11 where said switch means (120) comprises two switches (120), both of which must be activated to delay such connection. 65
13. The device as defined in claim 1 which includes an automatic voice signal generating means (130) actuated by the discrimination means for advising the patient of information pertinent to the detection of a treatable arrhythmia. 70
14. The device as defined in claim 13 wherein the generating means (130) is adapted to deliver a warning of an impending high energy shock. 75

15. The device as defined in claim 1 wherein the discriminating means includes memory for converting signals received from the monitoring means (20, 22) indicative of an excessively fast heart rate into a command for the energy source (24) to supply high energy shock treatment to the heart through the electrode means (32). 5

16. The device as defined in claim 1 wherein the discrimination means includes memory means (118) for converting signals received from the monitoring means (20, 22) indicative of an excessively slow heart rate into a command for the energy source (24) to supply pacing pulses to the heart through the electrode means (32). 10

17. The device as defined in claim 2 or 3 wherein the impedance reducing means includes a common actuator means operated by the discrimination means for applying the tightening means (124) and for delivering a conductive fluid (126). 15

18. The device as defined in claim 17 including spring biasing means (124) urging the actuator means toward a tightening means-applying and conductive fluid-delivering position, restraining means for the spring biasing means and trigger means operated by the discrimination means for releasing the restraining means. 20

19. The device as defined in claim 18 wherein the restraining means includes a heat destructable element (64) and the trigger means includes heating means (62) for destroying said element (64) and thereby releasing the spring biasing means (68). 25

20. The device as defined in claim 18, wherein a source (76) comprises at least one squeezable fluid capsule (76) and duct means (80) connecting the capsule (76) to a skin-contacting surface electrode means (84), and wherein the actuator means embraces the capsule (76) for movement therewith along by the spring biasing means (68) so as to squeeze fluid (126) from the capsule (76) through the duct means (80). 30

21. The device as defined in claim 18 including channel means (80, 82) in said surface (84) of the electrode means (32) for receiving fluid (126) from the duct means (80) and spreading same over the surface (84). 35

22. The device as defined in claim 18 wherein the actuator means includes plural actuators and the spring biasing means (68) urges the actuators apart to apply a tightening force to the harness or vest (202). 40

23. The device as defined in claim 10 wherein the 45

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5. impedance reducing means further includes chamber means (240) in the electrode means (218) for a capsule of conductive fluid (126), conduit means (254, 256) leading from the chamber means (240) to said interface and puncture means (246) operated by the expander means for puncturing a capsule (242) in the chamber means (240) responsive to expansion of the electrode means (218).

10. 24. The device as defined in claim 23 wherein the electrode means (218) includes a top plate (232), a compression plate (238) forming an upper wall of the chamber means (240) and a chamber base plate, wherein the puncture means (246) is connected with the compression plate (238) and wherein the expander means comprises an expansion spring (224) for separating the top plate (232) from the compression plate (238), thereby expanding the electrode means (218) causing the puncture means (246) to puncture a capsule (242) in the chamber means (240), and causing the capsule (242) to be squeezed between the compression plate (238) and the base plate so as to supply fluid (126) to the interface through the conduit means (254, 256).

20. 25. The device as defined in anyone of the preceding claims, which includes skin-contacting monitoring means (20, 22) for continuously monitoring heart rate and discrimination means for receiving signals from the monitoring means (20, 22) and comparing same with information in a memory (118) to determine the presence of a treatable arrhythmia.

25. 26. The device as defined in claim 25 wherein the discrimination means includes means for detecting heart rates below a preset value and the source of electrical energy (24) is adapted to apply pacing pulses to the electrode means (32) for raising the heart rate.

30. 27. The device as defined in claim 25 wherein the discrimination means includes means for detecting heart rates above a preset value and the source of electrical energy (24) is adapted to apply a defibrillating pulse to the electrode means (32) for effecting defibrillation.

35. 28. The device as defined in claim 25 wherein the body harness or vest (202) includes tightening means and a source of conductive fluid, and wherein the impedance reducing means includes means for applying the tightening means so as to increase pressure between the electrode means and the patient's skin, and the impedance reducing means further includes means for delivering the conductive fluid from the source to said interface.

40. 29. The device as defined in claim 1, wherein said elec-

trode means (32; 258) has a conductive surface adapted for contact with a patient's skin, for applying appropriate electrical pulses to the patient; and said impedance reducing means is contained within said electrode means (32; 258) and delivered to the patient's skin by said electrode means (32; 258) upon the sensing of a treatable arrhythmia for reducing the impedance between the conductive surface of the electrode means and the patient's skin.

30. The device as claimed in claim 29, wherein said impedance reducing means is a conductive fluid (126) released between the conductive surface of said electrode means (258) and the patient's skin.

31. The device as claimed in claim 30, wherein said conductive fluid (126) is contained in a housing comprising:

a fluid container chamber (240);
a fluid containing sac (242) located within said fluid container chamber (240); and
a puncture mechanism (246) for puncturing said fluid containing sac (242).

32. The device as claimed in claim 30 or 31, further comprising channel means (254, 256) in the conductive surface of said electrode means (258) for receiving the conductive fluid (126) and spreading the same over the conductive surface.

33. The device as claimed in anyone of the claims 29 to 32, wherein said electrode means (258) is adapted for sensing the existence of a treatable arrhythmia and applying appropriate electrical pulses automatically to the heart upon sensing of an arrhythmia.

34. The device according to any of claims 29 to 33 for use in a patient-worn body harness or vest (202) for applying electrical energy pulses externally to the patient in the treatment of a heart arrhythmia, the assembly including a pulsing electrode (258) having a skin-contacting surface, at least one squeezable capsule (242) containing a conductive electrode fluid (126), duct means (254, 256) connecting said capsule (242) to said surface of the electrode (258), a first actuator embracing the capsule (242), a second actuator, a spring-biasing means for urging the actuators apart, connectors for attaching the actuators to the harness whereby movement apart of the actuators by the spring biasing means provides a tightening force on the harness for increasing pressure between said surface and the patient's skin, and further provides movement of the first actuator along the capsule (242) to squeeze fluid (126) through the duct means (254, 256) and deliver

same to the said surface, restraining means for preventing the spring biasing means from moving the actuators apart, and trigger means for releasing the restraining means.

35. The device as defined in claim 34 including a second squeezable fluid capsule (242) embraced by the second actuator, and further duct means (254, 256) connecting the second capsule (242) to said surface of the electrode (258) for the delivery of fluid (126) thereto by movement of the second actuator along the fluid capsule (242).

36. The device as defined in claim 35 including channels (254) in the surface of the electrode (258) for spreading fluid (126) received through the duct means (254, 256) across said surface.

37. The device as defined in claim 34 wherein the restraining means includes a heat destructible element (64) and the trigger means includes a heater means (62) for destroying same.

38. The device as defined in claim 34 including an aperture in said surface of the pulsing electrode (258) and a sensing electrode (218) located in said aperture.

39. The assembly according to any of claims 29 to 33 for use in a patient-worn body harness or vest (202) for applying electrical energy pulses externally to the patient in the treatment of a heart arrhythmia, the assembly including a pulsing electrode (258) having a skin contacting surface, means defining a chamber (240) within the assembly for a capsule (242) of an electrically conducting fluid (126), the assembly having a cover portion remote from said skin contacting surface, a puncture means (246) for puncturing a capsule (242) within the chamber (240), conduit means (254, 256) connecting the chamber (240) with said skin contacting surface, pressure means (238) for squeezing the capsule (242), and expander means (244) for moving the cover structure away from said skin contacting surface, so as to increase the height of the assembly, while simultaneously operating the puncture means (246) and the pressure means (238).

40. The device as defined in claim 39 wherein the pressure means (238) comprises a pressure plate (238) forming an upper wall of the chamber (240) and to which the puncture means (246) is attached, and wherein the expander means (244) comprises an expansion spring (244) for separating the pressure plate (238) and cover structure thereby increasing the height of the assembly while decreasing the height of the chamber (240) and squeezing the capsule (242).

41. The device as defined in claim 40 wherein the puncture means (246) includes a curved needle carried by the pressure plate (238) for puncturing the capsule (242) from below on downward movement of the pressure plate (238). 5

42. The device as defined in claim 39 in combination with a body harness or vest (202) which includes pocket means (204) for receipt of the assembly and pocket closure means (206) for releasably encapsulating the assembly in the pocket means (204). 10

43. The device as defined in claim 39 wherein the expander means comprises an expandable pneumatic chamber means within the electrode structure and a source of fluid pressure (310) for supplying fluid to said chamber means whereby the chamber means is expanded upon the detection of a treatable arrhythmia. 15

44. The device as defined in claim 43 wherein said source (310, 318) is contained within the electrode structure. 20

45. The device as defined in claim 43 wherein said source (310) is supported on the belt or harness. 25

46. The device as defined in claim 43 wherein the pneumatic chamber means has an expansion dimension sufficient to take up a maximum slack dimension of the vest or harness with a safety margin. 30

47. The device as defined in claim 43 which includes a maintenance subsystem for the belt or harness, said maintenance subsystem including a pneumatic connection permitting periodic inflation of the chamber means to ensure correct harness adjustment, and adequate expansion and leak-tight integrity of the chamber means. 40

48. The device as defined in claim 43 wherein the puncture means comprises means for heating a capsule in the chamber means so as to heat-rupture the capsule. 45

49. A maintenance system for a patient-worn device as defined in any of the preceding claims, including means interfacing with monitoring means (20, 22) and electrode means (32) of the patient-worn device (10) for testing operational status of the patient-worn device (10) and means for recording and storing the memory contents of the patient-worn device (10). 50

50. The maintenance system as defined in claim 49 having signal receiving and delivering means for interfacing with the monitoring means (20, 22) and the electrode means (32) for providing at least one 55

of the following functions, namely:

- automatic testing of the monitoring means (20, 22) with calibrated input signals;
- unloading of a memory forming part of the discriminating means;
- testing and recharging of the source of electrical energy;
- transmitting memory contents and sensed detection signals by telephone to remote health care personnel;
- allowing remote health care personnel to communicate by telephone with the patient to operate the patient-worn device (10); and
- serving as a high-volume memory storage element for patient and device data.

51. The maintenance system as defined in claim 49 wherein the maintenance system is in the form of a stand for receipt of a carrier means 202 of a patient-worn device in the form of an upper body harness or garment thereon with the signal receiving and delivery means on the stand in register with the monitoring means (20, 22) and electrode means (32) on the harness. 20

52. The maintenance system as defined in claim 51 wherein the maintenance system includes means for transmitting test data, memory contents, and patient arrhythmia detection signals via telephone to a remote health care facility. 25

Patentansprüche

- Patientengetragene Vorrichtung zur automatischen Abgabe einer elektrischen Therapie an das Herz bei dem Auftreten einer behandelbaren Herz-Arrhythmie mit:
 - einer Überwachungseinrichtung (20, 22) zum kontinuierlichen Erfassen des Herzstatus des Patienten,
 - einer hautkontakterenden Behandlungselektrodeneinrichtung (32),
 - einer elektrischen Energiequelle (24) zur Lieferung elektrischer Impulse an die Elektrodeneinrichtung (32),
 - einer Diskriminationseinrichtung zum Empfang von Signalen von der Überwachungseinrichtung (20, 22) und zur Bestimmung des Vorhandenseins einer zu behandelnden Herz-Arrhythmie, und
 - einer Schalteinrichtung, die durch die Diskriminationseinrichtung abhängig von der Detektion einer behandelbaren Arrhythmie betätigt wird, um die elektrische Energiequelle (24) mit der Elektrodeneinrichtung (32) zu verbinden und geeignete elektrische Impulse an das Herz anzulegen,

gekennzeichnet durch
eine impedanzreduzierende Einrichtung, die abhängig von der Detektion einer behandelbaren Herz-Arrhythmie durch die Diskriminationseinrichtung zur automatischen Reduzierung der Impedanz für den elektrischen Stromfluß an einer Zwischenfläche zwischen der Elektrodeneinrichtung (32) und der Haut des Patienten betätigt wird.

2. Vorrichtung nach Anspruch 1,
dadurch gekennzeichnet,
daß die Elektrodeneinrichtung (32) auf einer Trägereinrichtung (202) in der Form eines Oberkörpergurtzeugs oder eines Kleidungsstückes getragen wird, und
daß die impedanzreduzierende Einrichtung eine Einrichtung aufweist, um die Trägereinrichtung (202) zu straffen, wodurch die Elektrodeneinrichtung (32) gegen die Haut gepreßt wird.

3. Vorrichtung nach Anspruch 1,
dadurch gekennzeichnet,
daß diese eine Quelle (242) elektrisch leitenden Fluidmaterials (126) aufweist, und
daß die impedanzreduzierende Einrichtung eine Einrichtung aufweist, um das elektrisch leitende Material von der Quelle (242) freizugeben und dieses an die Zwischenfläche zwischen der Elektrodeneinrichtung (32) und der Haut des Patienten zu bringen.

4. Vorrichtung nach Anspruch 1,
dadurch gekennzeichnet,
daß die Vorrichtung (10) als ein Körpergurtzeug ausgebildet ist, welches einen brustumfassenden Gurt (14) und einen Schulterriemen (18) aufweist,
daß die Überwachungseinrichtung (20, 22) jeweils wenigstens eine Überwachungseinheit auf dem Gurt (14) und dem Riemen (18) umfaßt, und
daß die Elektrodeneinrichtung (32) jeweils wenigstens eine Impulselektrode auf dem Gurt (14) und dem Riemen (18) aufweist.

5. Vorrichtung nach Anspruch 4,
dadurch gekennzeichnet,
daß bei Kombination mit einer Unterbekleidung (34), über welcher die Vorrichtung (10) getragen wird, die Unterbekleidung Öffnungen (36) für die Überwachungseinheiten (22) und die Elektroden (32) aufweist.

6. Vorrichtung nach Anspruch 4,
dadurch gekennzeichnet,
daß das Gurtzeug eine elastische Einrichtung aufweist und längerverstellbar ist, um eine kontrollierte Druckkraft gegen den Körper durch die Überwachungseinrichtung (20, 22) auszuüben, welche zum Erlangen zuverlässiger elektrokardiografischer Signale ausreichend ist.

7. Vorrichtung nach Anspruch 4,
dadurch gekennzeichnet,
daß der Brustgurt (14) eine Einrichtung zum Messen der Brustbewegung beim Atmen aufweist.

8. Vorrichtung nach Anspruch 1,
dadurch gekennzeichnet,
daß die Vorrichtung ein Gurtzeug oder eine Weste (202), eine Untereinheit, welche die Elektrodeneinrichtung (32), die Diskriminationseinrichtung und eine Leitungseinrichtung enthält, welche die Elektrodeneinrichtung (32) mit der Diskriminationseinrichtung verbindet, und eine Einrichtung (204, 206) zum lösbaren Befestigen der Untereinheit an dem Gurtzeug oder der Weste (202) aufweist.

9. Vorrichtung nach Anspruch 8,
dadurch gekennzeichnet,
daß die Einrichtung (204, 206) zum lösbaren Befestigen der Untereinheit an der Weste (202) eine Tascheneinrichtung (204) an der Weste (202) aufweist, um die Elektrodeneinrichtung (32, 218) aufzunehmen und zu halten.

10. Vorrichtung nach Anspruch 9,
dadurch gekennzeichnet,
daß die impedanzreduzierende Einrichtung eine Einrichtung (232) zum Ausdehnen der Elektrodeneinrichtung (218) innerhalb der Tascheneinrichtung (204) aufweist, wodurch die Elektrodeneinrichtung (218) mit erhöhtem Druck an die Haut des Patienten angelegt ist.

11. Vorrichtung nach Anspruch 1,
dadurch gekennzeichnet,
daß eine signalerzeugende Einrichtung (130, 132), die durch die Diskriminationseinrichtung abhängig von der Detektion einer zu behandelnden Arrhythmie betätigt wird, um den Patienten zu warnen, und eine patientenaktivierte Schalteinrichtung (120) vorgesehen sind, um die Verbindung der Energiequelle mit der Elektrodeneinrichtung (32) zu verzögern.

12. Vorrichtung nach Anspruch 11,
dadurch gekennzeichnet,
daß die Schalteinrichtung (120) zwei Schalter (120) aufweist, von denen beide aktiviert werden müssen, um eine derartige Verbindung zu verzögern.

13. Vorrichtung nach Anspruch 1,
dadurch gekennzeichnet,
daß eine automatische Stimmsignal-Erzeugungseinrichtung (130) vorgesehen ist, die durch die Diskriminationseinrichtung betätigt wird, um dem Patienten Informationen passend zu der Detektion einer zu behandelnden Arrhythmie zu geben.

14. Vorrichtung nach Anspruch 13,

dadurch gekennzeichnet,
daß die Erzeugungseinrichtung (130) zur Abgabe
einer Warnung eines bevorstehenden Hochener-
gieschocks ausgelegt ist.

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15. Vorrichtung nach Anspruch 1,
dadurch gekennzeichnet,
daß die Diskriminationseinrichtung einen Speicher
aufweist, um Signale, die von der Überwachungs-
einrichtung (20, 22) als Hinweis auf eine übermäßig
hohe Herzfrequenz empfangen werden, in einen
Befehl für die Energiequelle (24) zu konvertieren,
um durch die Elektrodeneinrichtung (32) das Herz
mit einer Hochenergieschockbehandlung zu ver-
sorgen.

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16. Vorrichtung nach Anspruch 1,
dadurch gekennzeichnet,
daß die Diskriminationseinrichtung eine Speicher-
einrichtung (118) aufweist, um Signale, die von der
Überwachungseinrichtung (20, 22) als Hinweis auf
eine zu niedrige Herzfrequenz empfangen werden,
in einen Befehl für die Energiequelle (24) zu kon-
vertieren, um durch die Elektrodeneinrichtung (32)
Schrittmacherimpulse an das Herz abzugeben.

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17. Vorrichtung nach Anspruch 2 oder 3,
dadurch gekennzeichnet,
daß die impedanzreduzierende Einrichtung eine
herkömmliche Betätigungseinrichtung aufweist, die
durch die Diskriminationseinrichtung betrieben
wird, um die Straffungseinrichtung (124) anzuwen-
den und ein leitendes Fluid (126) abzugeben.

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18. Vorrichtung nach Anspruch 17,
dadurch gekennzeichnet,
daß eine federgespannte Einrichtung (124) zum
Drücken der Betätigungseinrichtung zu einer Position,
in der die Straffungseinrichtung angewendet
und das leitende Fluid abgegeben wird, eine Rück-
halteinrichtung für die federgespannte Einrichtung
und eine Triggereinrichtung vorgesehen sind,
die durch die Diskriminationseinrichtung zum
Lösen der Rückhalteinrichtung betrieben wird.

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19. Vorrichtung nach Anspruch 18,
dadurch gekennzeichnet,
daß die Rückhalteinrichtung ein hitzezerstörbares
Element (64) aufweist, und daß die Triggereinrich-
tung eine Heizeinrichtung (62) aufweist, um das
Element (64) zu zerstören und dadurch die feder-
gespannte Einrichtung (68) zu lösen.

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20. Vorrichtung nach Anspruch 18,
dadurch gekennzeichnet,
daß eine Quelle (76) wenigstens eine ausdrück-
bare Fluidkapsel (76) und eine Kanaleinrichtung
(80) aufweist, welche die Kapsel (76) mit einer
hautkontakteierenden Elektrodeneinrichtungsfläche

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(84) verbindet, und daß die Betätigungseinrichtung
die Kapsel (76) zum Bewegen entlang dieser durch
die federgespannte Einrichtung (68) umschließt,
um das Fluid (126) aus der Kapsel (76) durch die
Kanaleinrichtung (80) auszudrücken.

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21. Vorrichtung nach Anspruch 18,
dadurch gekennzeichnet,
daß Rilleneinrichtungen (80, 82) in der Fläche (84)
der Elektrodeneinrichtung (32) vorgesehen sind,
um von der Kanaleinrichtung (80) das Fluid (126)
aufzunehmen und dieses über der Oberfläche (84)
zu verteilen.

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22. Vorrichtung nach Anspruch 18,
dadurch gekennzeichnet,
daß die Betätigungseinrichtung eine Vielzahl von
Betätigungsseinheiten aufweist, und daß die feder-
gespannte Einrichtung (68) die Betätigungsseinhei-
ten beiseite drückt, um eine Straffungskraft an dem
Gurtzeug oder der Weste (202) anzulegen.

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23. Vorrichtung nach Anspruch 10,
dadurch gekennzeichnet,
daß die impedanzreduzierende Einrichtung weiter
eine Kammerseinrichtung in der Elektrodeneinrich-
tung (218) für eine Kapsel des leitenden Fluides
(126), eine Kanaleinrichtung (254, 256), welche
von der Kammerseinrichtung (240) zu der Zwischen-
fläche führt, und eine Punktiereneinrichtung (246) auf-
weist, welche durch die Ausdehneinrichtung zum
Punktieren einer Kapsel (242) in der Kammersein-
richtung (240) abhängig von einer Ausdehnung der
Elektrodeneinrichtung (218) betrieben wird.

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24. Vorrichtung nach Anspruch 23,
dadurch gekennzeichnet,
daß die Elektrodeneinrichtung (218) eine Kopf-
platte (232), eine Druckplatte (238) zum Bilden der
oberen Wand der Kammerseinrichtung (240) und
eine Kammerfußplatte aufweist,
daß die Punktiereneinrichtung (246) mit der Druck-
platte (238) verbunden ist, und
daß die Ausdehneinrichtung eine Ausdehnfeder
(224) zum Trennen der Kopfplatte (232) von der
Druckplatte (238) aufweist, wodurch die Elektro-
deneinrichtung (218) ausgedehnt wird, wobei die
Punktiereneinrichtung (246) zum Punktieren der Kap-
sel (242) in der Kammerseinrichtung (240) veranlaßt
wird und bewirkt wird, daß die Kapsel (242) zwi-
schen der Druckplatte (238) und der Fußplatte aus-
gedrückt wird, um Fluid (126) durch die
Kanaleinrichtung (254, 256) an die Zwischenfläche
abzugeben.

25. Vorrichtung nach einem der vorhergehenden
Ansprüche,
dadurch gekennzeichnet,
daß eine hautkontakteierende Überwachungsein-

richtung (20, 22) zur kontinuierlichen Überwachung der Herzfrequenz und eine Diskriminationseinrichtung zum Empfangen von Signalen von der Überwachungseinrichtung (20, 22) und zum Vergleichen dieser mit Informationen in einem Speicher (118) vorgesehen sind, um das Vorhandensein einer zu behandelnden Arrhythmie zu bestimmen.

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26. Vorrichtung nach Anspruch 25,
dadurch gekennzeichnet,
daß die Diskriminationseinrichtung eine Einrich-
tung zum Ermitteln der Herzfrequenzen unterhalb
eines vorgegebenen Wertes aufweist, und daß die
elektrische Energiequelle (24) zum Anlegen von
Schrittmacherimpulsen an die Elektrodeneinrich-
tung (32) ausgelegt ist, um die Herzfrequenz zu
erhöhen.

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27. Vorrichtung nach Anspruch 25,
dadurch gekennzeichnet,
daß die Diskriminationseinrichtung eine Einrich-
tung zum Ermitteln von Herzfrequenzen oberhalb
eines vorgegebenen Wertes aufweist, und daß die
elektrische Energiequelle (24) zum Anlegen von
Defibrillationsimpulsen an die Elektrodeneinrich-
tung ausgelegt ist, um eine Defibrillation zu bewir-
ken.

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28. Vorrichtung nach Anspruch 25,
dadurch gekennzeichnet,
daß das Körpurgurtzeug oder die Weste (202) eine
Straffungseinrichtung und eine Quelle leitenden
Fluides aufweist, und
daß die impedanzreduzierende Einrichtung eine
Einrichtung zum Anwenden der Straffungseinrich-
tung aufweist, um den Druck zwischen der Elektro-
deneinrichtung und der Haut des Patienten zu
erhöhen, und
daß die impedanzreduzierende Einrichtung weiter
eine Einrichtung zum Abgeben des leitenden Flui-
des von der Quelle an die Zwischenfläche aufweist.

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29. Vorrichtung nach Anspruch 1,
dadurch gekennzeichnet,
daß Elektrodeneinrichtung (32; 258) eine leitende
Fläche aufweist, welche zum Kontakt mit der Haut
eines Patienten ausgelegt ist, um an dem Patienten
geeignete elektrische Impulse anzulegen, und
daß die impedanzreduzierende Einrichtung inner-
halb der Elektrodeneinrichtung (32, 258) angeord-
net und durch die Elektrodeneinrichtung (32; 258)
ein Erfassen einer zu behandelnden Arrhythmie an
die Haut des Patienten gebracht ist, um die Impe-
danz zwischen der leitenden Fläche der Elektro-
deneinrichtung und der Haut des Patienten zu
reduzieren.

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30. Vorrichtung nach Anspruch 29,
dadurch gekennzeichnet,

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31. Vorrichtung nach Anspruch 30,
dadurch gekennzeichnet,
daß das leitende Fluid (126) in einem Gehäuse ent-
halten ist, welches eine Fluidbehälterkammer (240), einen fluidenthaltenden Sack (242), der in
der Fluidbehälterkammer (240) angeordnet ist, und
einen Punktiermechanismus (246) zum Punktieren
des fluidenthaltenden Sacks (242) aufweist.

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32. Vorrichtung nach Anspruch 30 oder 31,
dadurch gekennzeichnet,
daß weiter eine Rilleneinrichtung (254, 256) in der
leitenden Fläche der Elektrodeneinrichtung (258)
vorgesehen ist, um das leitende Fluid (126) aufzu-
nehmen und dieses über die leitende Fläche zu
verteilen.

33. Vorrichtung nach einem der Ansprüche 29 bis 32,
dadurch gekennzeichnet,
daß die Elektrodeneinrichtung (258) zum Erfassen
des Vorhandenseins einer zu behandelnden
Arrhythmie und zum automatischen Anlegen geeig-
neter elektrischer Impulse an das Herz bei Erfas-
sen einer Arrhythmie ausgelegt ist.

34. Vorrichtung nach einem der Ansprüche 29 bis 33,
dadurch gekennzeichnet,
daß diese zum Gebrauch mit einem patientengetra-
genen Körpurgurtzeug oder einer Weste (202) zum
externen Anlegen elektrischer Energieimpulse an
den Patienten zu der Behandlung einer Herzarrhyth-
mie vorgesehen ist, und daß die Vorrichtung:

- eine Impulselektrode (258) mit einer hautkon-
taktierenden Fläche,
- wenigstens eine ausdrückbare Kapsel (242),
welche ein leitendes Elektrodenfluid (126)
beinhaltet,
- eine Kanaleinrichtung (254, 256), welche die
Kapsel (242) mit der Fläche der Elektrode
(258) verbindet,
- eine erste Betätigungsseinheit, welche die Kap-
sel (242) umfaßt,
- eine zweite Betätigungsseinheit,
- eine federgespannte Einrichtung zum Ausein-
anderdrücken der Betätigungsseinheiten,
- Verbindungseinheiten zum Befestigen der
Betätigungsseinheiten an dem Gurtzeug, wobei
eine Auseinanderbewegung der Betätigungs-
einheiten durch die federgespannte Einrich-
tung eine Straffungskraft an dem Gurtzeug zur
Erhöhung des Drucks zwischen der Fläche und
der Haut des Patienten bewirkt, und weiterhin
eine Bewegung der ersten Betätigungsseinheit

entlang der Kapsel (242) bewirkt, um durch die Kanaleinrichtung (254, 256) Fluid (126) auszudrücken, und dieses an die Fläche abzugeben, eine Rückhalteinrichtung zum Hindern der federgespannten Einrichtung, die Betätigungs-⁵ einheiten auseinanderzubewegen, und eine Trigger-Einrichtung zum Lösen der Rück- halteinrichtung aufweist.¹⁰

35. Vorrichtung nach Anspruch 34, dadurch gekennzeichnet,
daß eine zweite ausdrückbare Fluidkapsel (242), welche durch die zweite Betätigungsseinheit umfaßt ist, und eine weitere Kanaleinrichtung (254, 256) vorgesehen sind, welche die zweite Kapsel (242) mit der Fläche der Elektrode (258) verbindet, um Fluid (126) dorthin durch eine Bewegung der zweiten Betätigungsseinheit entlang der Fluidkapsel (242) abzugeben.¹⁵

36. Vorrichtung nach Anspruch 35, dadurch gekennzeichnet,
daß Rillen (254) in der Fläche der Elektrode (258) vorgesehen sind, um über die Fläche das Fluid (126) zu verteilen, welches von der Kanaleinrich-²⁰ tung (254, 256) aufgenommen wurde.

37. Vorrichtung nach Anspruch 34,
dadurch gekennzeichnet,
daß die Rückhalteinrichtung ein hitzezerstörbares Element (64) aufweist, und
daß zu dessen Zerstörung die Triggereinrichtung eine Heizeinrichtung (62) aufweist.²⁵

38. Vorrichtung nach Anspruch 34,
dadurch gekennzeichnet,
daß eine Öffnung in der Fläche der Impulselektrode (258) vorgesehen ist, und daß eine Sensorelek-³⁰ trode (218) in der Öffnung angeordnet ist.

39. Vorrichtung nach einem der Ansprüche 29 bis 33, dadurch gekennzeichnet,
daß diese zur Verwendung an einem patientenge-³⁵ tragenen Körpergurtzeug oder einer Weste (202) zum externen Anlegen elektrischer Energieimpulse an den Patienten bei der Behandlung einer Herz- Arrhythmie vorgesehen ist, und daß

- eine Impulselektrode (258) mit einer hautkon-⁴⁰ taktierenden Fläche,
- eine Einrichtung, die eine Kammer (240) inner-⁴⁵ halb der Vorrichtung für eine Kapsel (242) eines elektrisch leitenden Fluides (126) defi- niert,
- ein Deckbereich entfernt von der hautkontak-⁵⁰ tierenden Fläche,
- eine Punktireinrichtung (246) zum Punktieren

einer Kapsel (242) innerhalb der Kammer (240),
- eine Kanaleinrichtung (254, 256), welche die Kammer (240) mit der hautkontakteierenden Fläche verbindet,
- eine Druckeinrichtung (238) zum Ausdrücken der Kapsel (242), und
- eine Aufweiteinrichtung (244) zum Bewegen des Deckbereichs von der hautkontakteierenden Fläche weg aufweist, um die Höhe der Vorrich-⁵ tung zu vergrößern, während gleichzeitig die Punktireinrichtung (246) und die Druckein- richung (238) betrieben werden, vorgesehen sind.

40. Vorrichtung nach Anspruch 39,
dadurch gekennzeichnet,
daß die Druckeinrichtung (238) eine Druckplatte (238) aufweist, welche eine obere Wand der Kammer (240) bildet, und an der die Punktireinrichtung (246) befestigt ist, und
daß die Ausdehneinrichtung (244) eine Ausdehnfe-¹⁰ der (244) zum Trennen der Druckplatte (238) und des Deckbereichs aufweist, wodurch die Höhe der Vorrichtung vergrößert wird, während die Höhe der Kammer (240) verringert und die Kapsel (242) aus- gedrückt wird.

41. Vorrichtung nach Anspruch 40,
dadurch gekennzeichnet,
daß die Punktireinrichtung (246) eine gebogene Nadel aufweist, welche von der Druckplatte (238) zum Punktieren der Kapsel (242) von unten bei einer Nachuntenbewegung der Druckplatte (238) gehalten ist.¹⁵

42. Vorrichtung nach Anspruch 39,
dadurch gekennzeichnet,
daß eine Kombination mit einem Körpergurtzeug oder einer Weste (202) vorgesehen ist, welche eine Tascheinrichtung (204) zur Aufnahme der Vor-²⁰ richtung und eine Taschenverschlußeinrichtung (206) zum lösbar Einschließen der Vorrichtung in der Tascheinrichtung (204) aufweist.

43. Vorrichtung nach Anspruch 39,
dadurch gekennzeichnet,
daß die Ausdehneinrichtung eine ausdehbare pneumatische Kammereinrichtung innerhalb der Elektrodenanordnung und eine Flumdruckquelle (310) zum Abgeben von Fluid an die Kammerein- richung aufweist, wodurch die Kammereinrichtung bei Detektion einer behandelbaren Arrhythmie aus-²⁵ gedeht wird.

44. Vorrichtung nach Anspruch 43,
dadurch gekennzeichnet,
daß die Quelle (310, 318) innerhalb der Elektroden-³⁰ anordnung angeordnet ist.

45. Vorrichtung nach Anspruch 43,
dadurch gekennzeichnet,
daß die Quelle (310) auf dem Gurt oder dem Gurtzeug angebracht ist. 5

46. Vorrichtung nach Anspruch 43,
dadurch gekennzeichnet,
daß die pneumatische Kammereinrichtung eine Aufweit-Schlaffheit die Größe der Weste oder des Gurtzeugs mit einer Sicherheitsmarke aufzufüllen. 10

47. Vorrichtung nach Anspruch 43,
dadurch gekennzeichnet,
daß für den Gurt oder das Gurtzeug ein Wartungsundersystem vorgesehen ist, welches eine pneumatische Verbindung aufweist, die ein periodisches Aufblasen der Kammereinrichtung zur Sicherstellung einer richtigen Gurtzeugeinstellung, eine adäquate Ausdehnung und eine Dichtigkeit der Kammereinrichtung gewährleistet. 15 20

48. Vorrichtung nach Anspruch 43,
dadurch gekennzeichnet,
daß die Punktierenrichtung eine Einrichtung zum Heizen der Kapsel in der Kammereinrichtung aufweist, um ein Aufplatzen der Kapsel durch Hitze zu bewirken. 25

49. Wartungssystem für eine patientengetragene Vorrichtung nach einem der vorausgehenden Ansprüche,
dadurch gekennzeichnet,
daß zum Testen des Betriebsstatus der patientengetragenen Vorrichtung (10) eine Einrichtung, welche mit einer Überwachungseinrichtung (20, 22) und einer Elektrodeneinrichtung (32) der patientengetragenen Vorrichtung (10) verbunden ist, und eine Einrichtung zum Aufzeichnen und Speichern der Speicherinhalte der patientengetragenen Vorrichtung (10) vorgesehen sind. 30 35 40

50. Wartungssystem nach Anspruch 49,
dadurch gekennzeichnet,
daß eine Signalempfangs- und Erzeugungseinrichtung zum Verbinden zwischen der Überwachungseinrichtung (20, 22) und der Elektrodeneinrichtung (32) zum Bereitstellen wenigstens einer der folgenden Funktionen vorgesehen ist, nämlich:
 a) automatisches Testen der Überwachungseinrichtung (20, 22) mit kalibrierten Eingangssignalen;
 b) Entladen eines einen Speicher bildenden Teils der Diskriminationseinrichtung;
 c) Testen und Wiederaufladen der elektrischen Energiequelle;
 d) Übermitteln der Speicherinhalte und der gemessenen Detektionssignale über Telefon zu entferntem medizinischen Fachpersonal; 50 55

e) Gewährleisten einer Kommunikation über Telefon des entfernten medizinischen Fachpersonals mit dem Patienten, um die patientengeogene Vorrichtung (10) zu betätigen;
 f) Gewährleisten eines Speicherelements mit großem Speichervolumen für Patienten- und Vorrichtungsdaten.

51. Wartungssystem nach Anspruch 49,
dadurch gekennzeichnet,
daß das Wartungssystem als ein Ständer zur Aufnahme einer Trägereinrichtung (202) einer als ein Oberkörpergurtzeug oder ein Kleidungsstück ausgeformten patientengetragener Vorrichtung ausgebildet ist, wobei die Signalempfangs- und Erzeugungseinrichtung auf dem Ständer in Dekkung mit der Überwachungseinrichtung (20, 22) und der Elektrodeneinrichtung (32) des Gurtzeugs ist.

52. Wartungssystem nach Anspruch 51,
dadurch gekennzeichnet,
daß eine Einrichtung zum Übermitteln von Testdaten, Speicherinhalten und Detektionssignalen von Patientenarrhythmien über Telefon zu einer entfernten medizinischen Facheinrichtung vorgesehen ist.

Revendications

1. Dispositif porté par un patient destiné à administrer automatiquement une électrothérapie au cœur si survient une arythmie cardiaque réclamant traitement, le dispositif comprenant : des moyens de monitorage (20, 22) pour sonder en continu l'état du cœur du patient, des moyens d'électrodes de traitement (32) en contact avec la peau, une source d'énergie électrique (24) destinée à fournir des impulsions électriques aux moyens d'électrodes (32), des moyens de discrimination pour recevoir des signaux en provenance des moyens de monitorage (20, 22) et déterminer la présence d'une arythmie cardiaque réclamant traitement, et des moyens de commutation enclenchés par les moyens de discrimination en réponse à la détection d'une arythmie réclamant traitement, destinés à raccorder la source d'énergie électrique (24) aux moyens d'électrodes (32) et à appliquer au cœur les impulsions électriques appropriées, ledit dispositif porté par un patient étant caractérisé par des moyens de réduction de l'impédance enclenchés par les moyens de discrimination en réponse à la détection d'une arythmie cardiaque réclamant traitement, destinés à réduire automatiquement l'impédance à la circulation du courant électrique au niveau d'une interface entre les moyens d'électrodes (32) et la peau du patient.
2. Dispositif selon la Revendication 1, dans lequel les

moyens d'électrodes (32) sont portés par des moyens de support (202) sous forme d'un harnais ou d'un vêtement pour le haut du corps et les moyens de réduction de l'impédance comprennent des moyens pour resserrer les moyens de support (202) et, de ce fait, presser les moyens d'électrode (32) contre la peau.

3. Dispositif selon la Revendication 1, qui comprend une source (242) de matériau fluide électroconducteur (126) et dans lequel les moyens de réduction de l'impédance comprennent des moyens pour libérer de ladite source (242) le matériau électroconducteur et le faire sortir à l'interface entre les moyens d'électrodes (32) et la peau du patient.

4. Dispositif selon la Revendication 1, dans lequel le dispositif (10) sous forme d'un harnais corporel comprend une ceinture (14) entourant la poitrine et une bretelle (18), dans lequel les moyens de monitorage (20, 22) comprennent au moins un moniteur sur chacune de ladite ceinture (14) et de ladite bretelle (18), et dans lequel les moyens d'électrode (32) comprennent au moins une électrode d'impulsion sur chacune de ladite ceinture (14) et de ladite bretelle (18).

5. Dispositif selon la Revendication 4 en combinaison avec un sous-vêtement (34) au dessus duquel doit être porté le dispositif (10), le sous-vêtement comportant des ouvertures (36) pour les moniteurs (22) et les électrodes (32).

6. Dispositif selon la Revendication 4 dans lequel le harnais comprend des moyens élastiques et est réglable en longueur pour faire exercer une force de compression contrôlée contre le corps par les moyens de monitorage (20, 22) suffisante pour acquérir des signaux électrocardiographiques fiables.

7. Dispositif selon la Revendication 4 dans lequel la ceinture (14) de poitrine comprend des moyens pour mesurer le déplacement de la cage thoracique pendant la respiration.

8. Dispositif selon la Revendication 1, dans lequel le dispositif comprend un harnais ou un gilet (202), un sous-ensemble comprenant les moyens d'électrodes (32), les moyens de discrimination et des moyens conducteurs reliant les moyens d'électrodes (32) aux moyens de discrimination, et des moyens (204, 206) pour fixer de manière libérable le sous-ensemble sur le harnais ou le gilet (202).

9. Dispositif selon la Revendication 8, dans lequel les moyens (204, 206) pour fixer de manière libérable le sous-ensemble sur le gilet (202) comprennent des moyens de poche (204) dans le gilet (202) des-
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tinés à recevoir et retenir les moyens d'électrodes (32, 218).

10. Dispositif selon la Revendication 9, dans lequel les moyens de réduction de l'impédance comprennent des moyens (232) pour dilater des moyens d'électrodes (218) à l'intérieur des moyens de poche (204) et ainsi appliquer contre la peau du patient les moyens d'électrodes (218) avec une pression accrue.

11. Dispositif selon la Revendication 1, qui comprend des moyens (130, 132) de génération de signaux commandés par les moyens de discrimination en réponse à la détection d'une arythmie cardiaque réclamant traitement, destinés à prévenir le patient, et un moyen d'interrupteur (120) commandé par le patient pour retarder la connexion de la source d'énergie aux moyens d'électrodes (32).

12. Dispositif selon la Revendication 11, où ledit moyen d'interrupteur (120) comprend deux interrupteurs (120) qui doivent tous deux être activés pour retarder cette connexion.

13. Dispositif selon la Revendication 1, qui comprend un moyen (130) de génération automatique de signaux vocaux commandé par les moyens de discrimination, destiné à porter à la connaissance du patient des informations pertinentes concernant la détection d'une arythmie réclamant traitement.

14. Dispositif selon la Revendication 13, dans lequel le moyen (130) de génération est apte à émettre un avertissement d'un choc d'énergie élevée imminent.

15. Dispositif selon la Revendication 1, dans lequel les moyens de discrimination comprennent des moyens de mémoire pour convertir les signaux reçus des moyens de monitorage (20, 22) indicatifs d'un rythme cardiaque exagérément rapide en une commande pour la source d'énergie (24) de fournir au cœur un traitement par choc d'énergie élevée par l'intermédiaire des moyens d'électrodes (32).

16. Dispositif selon la Revendication 1, dans lequel les moyens de discrimination comprennent des moyens de mémoire (118) pour convertir les signaux reçus des moyens de monitorage (20, 22) indicatifs d'un rythme cardiaque exagérément lent en une commande pour la source d'énergie (24) de fournir des impulsions stimulatrices au cœur par l'intermédiaire des moyens d'électrodes (32).

17. Dispositif selon la Revendication 2 ou 3, dans lequel le moyen de réduction de l'impédance comprend un moyen d'actionneur commun commandé par les moyens de discrimination pour l'application

des moyens de serrage (124) et pour délivrer un fluide conducteur (126).

18. Dispositif selon la Revendication 17, comprenant des moyens de charge par ressort (124) poussant le moyen d'actionneur vers une position d'application des moyens de serrage et de décharge du fluide conducteur, des moyens d'entrave pour les moyens de charge par ressort et des moyens de déclenchement commandés par les moyens de discrimination et destinés à libérer les moyens d'entrave. 5

19. Dispositif selon la Revendication 18, dans lequel les moyens d'entrave comprennent un élément (64) destructible par la chaleur et les moyens de déclenchement comprennent des moyens de chauffage (62) pour détruire ledit élément (64) et ainsi libérer les moyens de charge par ressort (68). 10

20. Dispositif selon la Revendication 18, dans lequel une source (76) comprend au moins une capsule (76) de fluide comprimable et des moyens de conduit (80) reliant la capsule (76) à des moyens d'électrodes (84) avec une surface en contact avec la peau ; et dans lequel le moyen d'actionneur embrasse la capsule (76) pour un déplacement le long de celle-ci grâce aux moyens de charge par ressort (68) afin d'exprimer le fluide (126) hors de la capsule (76) via les moyens de conduit (80). 15

21. Dispositif selon la Revendication 18 comprenant des moyens de canaux (80, 82) dans ladite surface (84) des moyens d'électrodes (32) pour recevoir le fluide (126) venant des moyens de conduit (80) et répandre celui-ci sur la surface (84). 20

22. Dispositif selon la Revendication 18, dans lequel les moyens d'actionneur comprennent plusieurs actionneurs et les moyens de charge par ressort (68) écartent les actionneurs pour appliquer une force de serrage au harnais ou gilet (202). 25

23. Dispositif selon la Revendication 10, dans lequel les moyens de réduction de l'impédance comprennent additionnellement des moyens de chambre (240) dans les moyens d'électrodes (218) pour une capsule de fluide conducteur (126), des moyens de conduit (254, 256) menant desdits moyens de chambre (240) à ladite interface et des moyens de perforation (246) commandés par les moyens de dilatation, destinés à perforent une capsule (242) dans les moyens de chambre (240) en réponse à la dilatation des moyens d'électrodes (218). 30

24. Dispositif selon la Revendication 23, dans lequel les moyens d'électrodes (218) comprennent une plaque supérieure (232), une plaque de compression (238) formant une paroi supérieure pour les 35

moyens de chambre (240) et une plaque de base de chambre, dans lequel les moyens de perforation (246) sont raccordés à la plaque de compression (238) et dans lequel les moyens de dilatation comprennent un ressort d'expansion (224) pour séparer la plaque supérieure (232) de la plaque de compression (238), et de ce fait la dilatation des moyens d'électrodes (218) faisant que les moyens de perforation (246) perforent une capsule (242) dans les moyens de chambre (240) et faisant que la capsule (242) est pressée entre la plaque de compression (238) et la plaque de base afin de fournir le fluide (126) à l'interface via les moyens de conduit (254, 256). 40

25. Dispositif selon l'une quelconque des Revendications précédentes, qui comprend des moyens de monitorage (20, 22) en contact avec la peau, destinés à surveiller en continu le rythme cardiaque, et des moyens de discrimination destinés à recevoir des signaux des moyens de monitorage (20, 22) et à comparer ceux-ci avec des informations contenues dans une mémoire (118) pour déterminer la présence d'une arythmie réclamant traitement. 45

26. Dispositif selon la Revendication 25, dans lequel les moyens de discrimination comprennent des moyens de détection des rythmes cardiaques inférieurs à une valeur prescrite et la source d'énergie électrique (24) est apte à appliquer des impulsions stimulatrices aux moyens d'électrodes (32) pour augmenter le rythme cardiaque. 50

27. Dispositif selon la Revendication 25, dans lequel les moyens de discrimination comprennent des moyens de détection des rythmes cardiaques supérieurs à une valeur prescrite et la source d'énergie électrique (24) est apte à appliquer des impulsions défibrillatrices aux moyens d'électrodes (32) pour effectuer une défibrillation. 55

28. Dispositif selon la Revendication 25, dans lequel le harnais corporel ou gilet (202) comprend des moyens de serrage et une source de fluide conducteur, et dans lequel les moyens de réduction de l'impédance comprennent des moyens pour appliquer les moyens de serrage afin d'accroître la pression entre les moyens d'électrodes et la peau du patient, et les moyens de réduction de l'impédance comprennent additionnellement des moyens pour délivrer le fluide conducteur de la source à ladite interface.

29. Dispositif selon la Revendication 1, dans lequel lesdits moyens d'électrodes (32 ; 258) comprennent une surface conductrice adaptée au contact avec la peau d'un patient, pour l'application d'impulsions électriques appropriées au patient ; et

lesdits moyens de réduction de l'impédance sont contenus à l'intérieur desdits moyens d'électrodes (32 ; 258) et administrés sur la peau du patient par lesdits moyens d'électrodes (32 ; 258) sur détection d'une arythmie réclamant traitement, afin de réduire l'impédance entre la surface conductrice des moyens d'électrodes et la peau du patient.

30. Dispositif selon la Revendication 29, dans lequel lesdits moyens de réduction de l'impédance sont un fluide (126) libéré entre la surface conductrice desdits moyens d'électrodes (258) et la peau du patient.

31. Dispositif selon la Revendication 30, dans lequel ledit fluide conducteur (126) est contenu dans un logement comprenant :

une chambre réservoir (240) pour le fluide ;
une poche (242) contenant le fluide, située à l'intérieur de ladite chambre réservoir (240) pour le fluide ; et
un mécanisme de perforation (246) pour perforen ladite poche (242) contenant le fluide.

32. Dispositif selon la Revendication 30 ou 31, comprenant additionnellement des moyens de canaux (254, 256) dans la surface conductrice desdits moyens d'électrodes (258) pour recevoir le fluide conducteur (126) et répandre celui-ci sur la surface conductrice.

33. Dispositif selon l'une quelconque des Revendications 29 à 32, dans lequel lesdits moyens d'électrodes (258) sont aptes à détecter l'existence d'une arythmie réclamant traitement et à appliquer automatiquement les impulsions électriques appropriées au cœur à détection d'une arythmie.

34. Dispositif selon l'une quelconque des Revendications 29 à 33, destiné à être utilisé dans un harnais corporel ou gilet (202) porté par un patient, pour appliquer des impulsions électriques de manière extérieure au patient dans le traitement d'une arythmie cardiaque, l'ensemble contenant une électrode d'impulsions (258) ayant une surface en contact avec la peau, au moins une capsule comprimable (242) contenant un fluide (126) conducteur pour électrode, des moyens de canalisation (254, 256) reliant ladite capsule (242) à ladite surface de l'électrode (258), un premier actionneur embrassant la capsule (242), un second actionneur, un moyen de charge par ressort pour séparer les actionneurs, des connecteurs pour attacher les actionneurs au harnais, ce par quoi un mouvement d'éloignement des actionneurs par le moyen de charge par ressort fournit une force de serrage sur le harnais pour accroître la pression entre ladite

surface et la peau du patient et, de plus, assure le déplacement du premier actionneur le long de la capsule (242) pour exprimer le fluide (126) via les moyens de conduit (254, 256) et délivrer celui-ci sur ladite surface, des moyens d'entrave pour empêcher les moyens de charge par ressort d'écartez les actionneurs, et des moyens de déclenchement pour libérer les moyens d'entrave.

35. Dispositif selon la Revendication 34 comprenant une seconde capsule de fluide comprimable (242) embrassée par le second actionneur et des moyens de conduit supplémentaires (254, 256) reliant la seconde capsule (242) à ladite surface de l'électrode (258) pour la fourniture du fluide (126) à celle-ci par déplacement du second actionneur le long de la capsule (242) de fluide.

36. Dispositif selon la Revendication 35 comprenant des canaux (254) dans la surface de l'électrode (258) pour répandre le fluide (126) reçu via les moyens de conduit (254, 256) sur ladite surface.

37. Dispositif selon la Revendication 34, dans lequel les moyens d'entrave comprennent un élément (64) destructible par la chaleur et les moyens de déclenchement comprennent un moyen de chauffage (62) pour détruire celui-ci.

38. Dispositif selon la Revendication 34, comprenant une ouverture dans ladite surface de l'électrode d'impulsion (258) et une électrode de détection (218) située dans ladite ouverture.

39. Ensemble selon l'une quelconque des Revendications 29 à 33, destiné à être utilisé dans un harnais corporel ou gilet (202) porté par un patient, pour appliquer des impulsions électriques de manière extérieure au patient dans le traitement d'une arythmie cardiaque, l'ensemble contenant une électrode d'impulsions (258) ayant une surface en contact avec la peau, des moyens définissant une chambre (240) à l'intérieur de l'ensemble pour une capsule (242) d'un fluide électroconducteur (126), l'ensemble ayant une partie formant couverture à distance de ladite surface en contact avec la peau, un moyen de perforation (246) pour perforen une capsule (242) à l'intérieur de la chambre (240), des moyens de conduit (254, 256) reliant la chambre (240) à ladite surface en contact avec la peau, des moyens de pression (238) pour presser la capsule (242) et des moyens de dilatation (244) pour faire partir la structure de couverture de ladite surface en contact avec la peau afin d'accroître la hauteur de l'ensemble, tout en mettant en action le moyen de perforation (246) et le moyen de pression (238).

40. Dispositif selon la Revendication 39, dans lequel les moyens de pression (238) comprennent une

plaqué de pression (238) formant une paroi supérieure pour la chambre (240) et à laquelle est fixé le moyen de perforation (246), et dans lequel les moyens de dilatation (244) comprennent un ressort d'expansion (244) pour séparer la plaque de pression (238) de la structure d'enveloppe, accroissant de ce fait la hauteur de l'ensemble tout en diminuant la hauteur de la chambre (240) et en pressant la capsule (242).

41. Dispositif selon la Revendication 40, dans lequel le moyen de perforation (246) comprend une aiguille courbe portée par la plaque de pression (238) destinée à percer la capsule (242) depuis le dessous par le mouvement vers le bas de la plaque de pression (238).

42. Dispositif selon la Revendication 39, en combinaison avec un harnais corporel ou un gilet (202) qui comporte des moyens de poche (204) pour recevoir l'ensemble et des moyens de fermeture (206) de poche pour enfermer l'ensemble de manière libérable dans les moyens de poche (204).

43. Dispositif selon la Revendication 39, dans lequel le moyen de dilatation comprend un moyen de chambre pneumatique dilatable à l'intérieur de la structure à électrodes et une source de pression (310) de fluide pour amener le fluide audit moyen de chambre, le moyen de chambre étant ainsi dilaté à détection d'une arythmie réclamant traitement.

44. Dispositif selon la Revendication 43, dans lequel ladite source (310, 318) est contenue à l'intérieur de la structure à électrodes.

45. Dispositif selon la Revendication 43, dans lequel ladite source (310) est maintenue sur la ceinture ou le harnais.

46. Dispositif selon la Revendication 43, dans lequel le moyen de chambre pneumatique possède une possibilité de dilatation suffisante pour remplir une dimension maximum de mou dans le gilet ou le harnais avec une marge de sécurité.

47. Dispositif selon la Revendication 43, qui comprend un module de maintenance pour la ceinture ou le harnais, ledit module de maintenance comprenant une connexion pneumatique permettant le gonflage périodique du moyen de chambre pour assurer un réglage correct du harnais, et la dilatation adéquate et l'intégrité de l'étanchéité du moyen de chambre.

48. Dispositif selon la Revendication 43, dans lequel le moyen de perforation comprend des moyens de chauffage d'une capsule dans le moyen de chambre afin de déchirer la capsule par la chaleur.

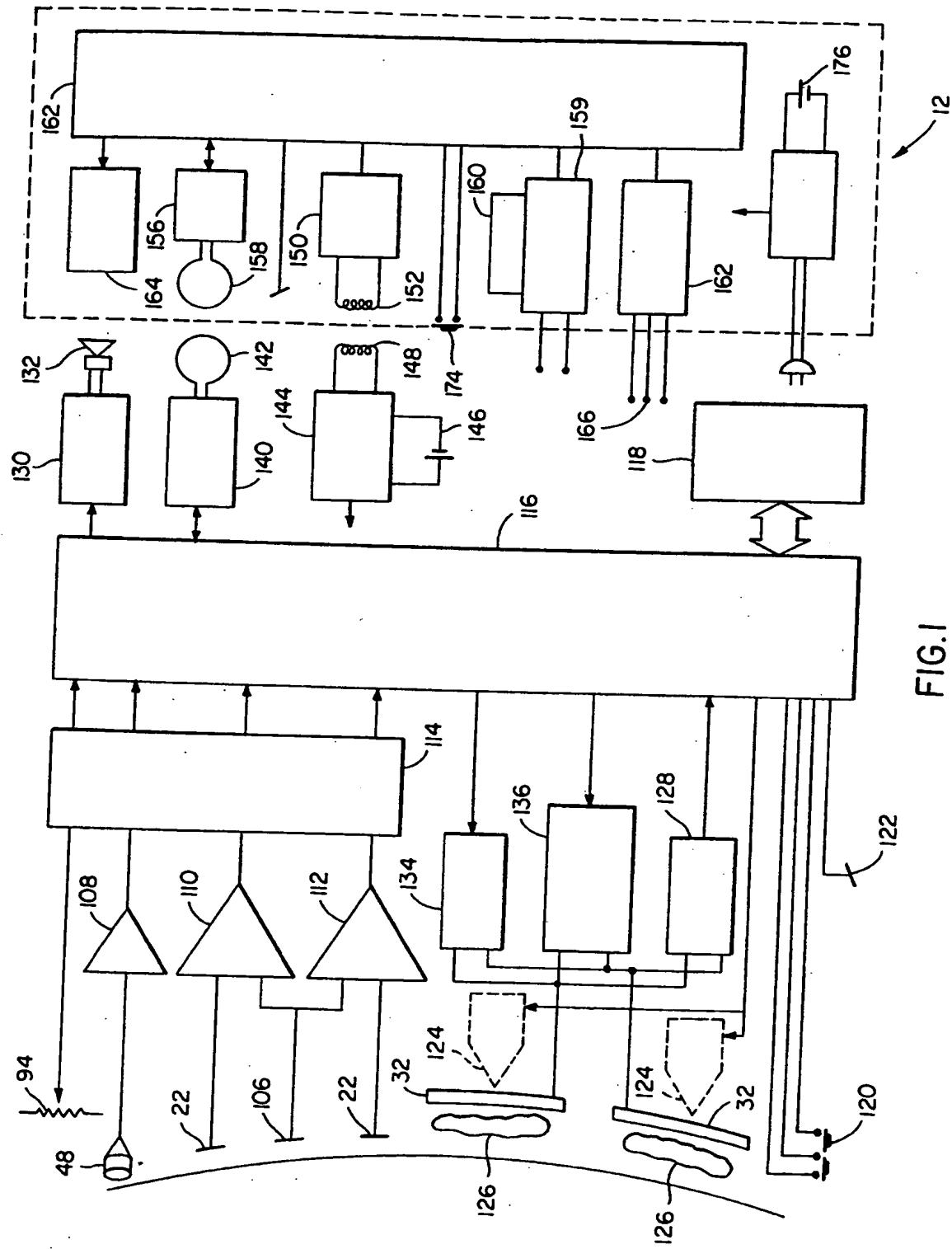
49. Système de maintenance pour un dispositif porté par un patient tel que défini dans l'une quelconque des Revendications précédentes, comprenant des moyens s'interfaisant avec les moyens de monitorage (20, 22) et les moyens d'électrodes (32) du dispositif (10) porté par le patient, destinés à vérifier le statut fonctionnel du dispositif (10) porté par le patient, et des moyens pour enregistrer et stocker les contenus mémoire du dispositif (10) porté par le patient.

50. Système de maintenance selon la Revendication 49, ayant des moyens de réception et d'émission de signaux pour un interfichage avec les moyens de monitorage (20, 22) et les moyens d'électrodes (32), et destinés à assurer au moins une des fonctions suivantes :

- a) test automatique des moyens de monitorage (20, 22) avec des signaux d'entrée calibrés ;
- b) décharge d'une mémoire faisant partie des moyens de discrimination ;
- c) test et recharge de la source d'énergie électrique ;
- d) transmission des contenus mémoire et des signaux de détection captés par téléphone vers du personnel médical motorisé éloigné ;
- e) autorisation pour le personnel médical éloigné de communiquer par téléphone avec le patient pour faire fonctionner le dispositif (10) porté par le patient ; et
- f) utilisation comme élément de stockage mémoire grand volume pour les données concernant le patient et le dispositif.

51. Système de maintenance selon la Revendication 49, dans lequel le système de maintenance se présente sous la forme d'une base destinée à recevoir un moyen de support (202) d'un dispositif porté par un patient sous forme d'un harnais ou vêtement pour le haut du corps, les moyens de réception et d'émission de signaux du support étant en correspondance exacte avec les moyens de monitorage (20, 22) et les moyens d'électrodes (32) sur le harnais.

52. Système de maintenance selon la Revendication 51, dans lequel le système de maintenance comprend des moyens pour transmettre des données de test, des contenus mémoire et des signaux de détection d'une arythmie chez un patient à une unité de soins médicaux éloignée via un téléphone.



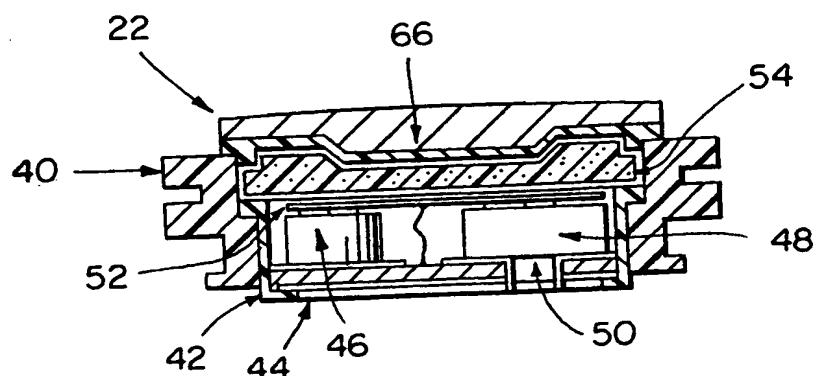


FIG. 2a

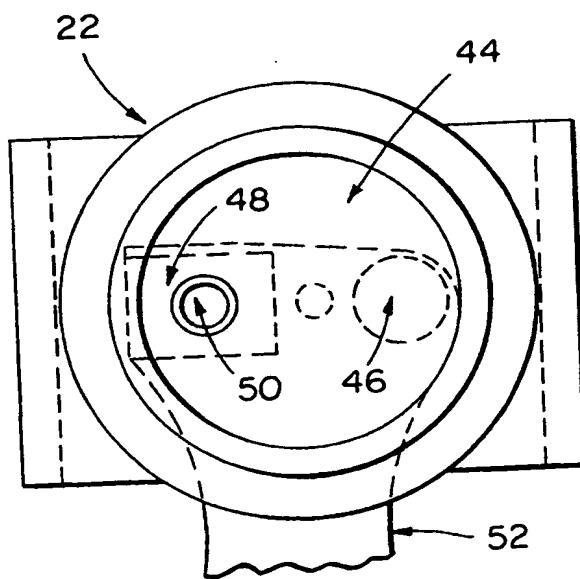


FIG. 2b

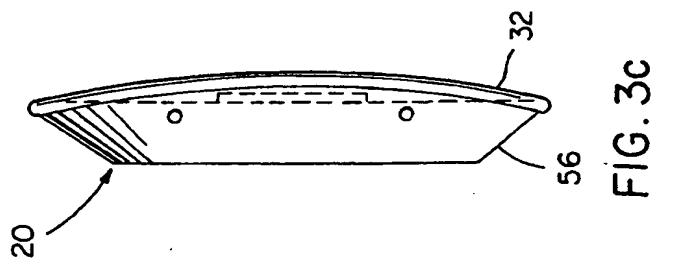


FIG. 3c

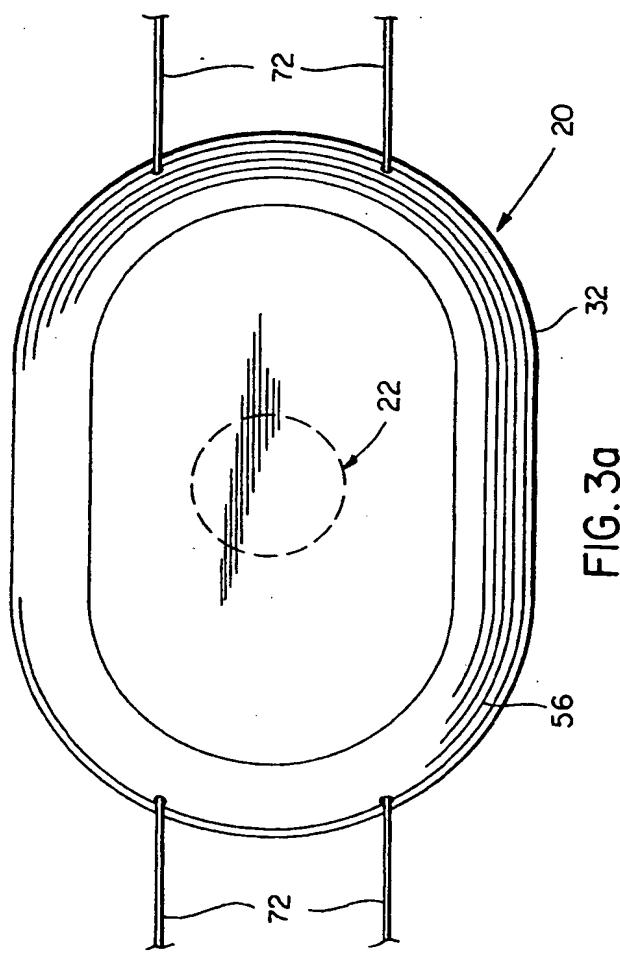


FIG. 3a

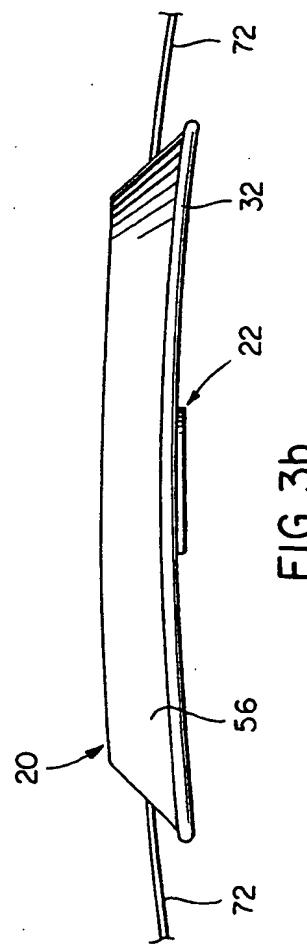


FIG. 3b

FIG. 3d

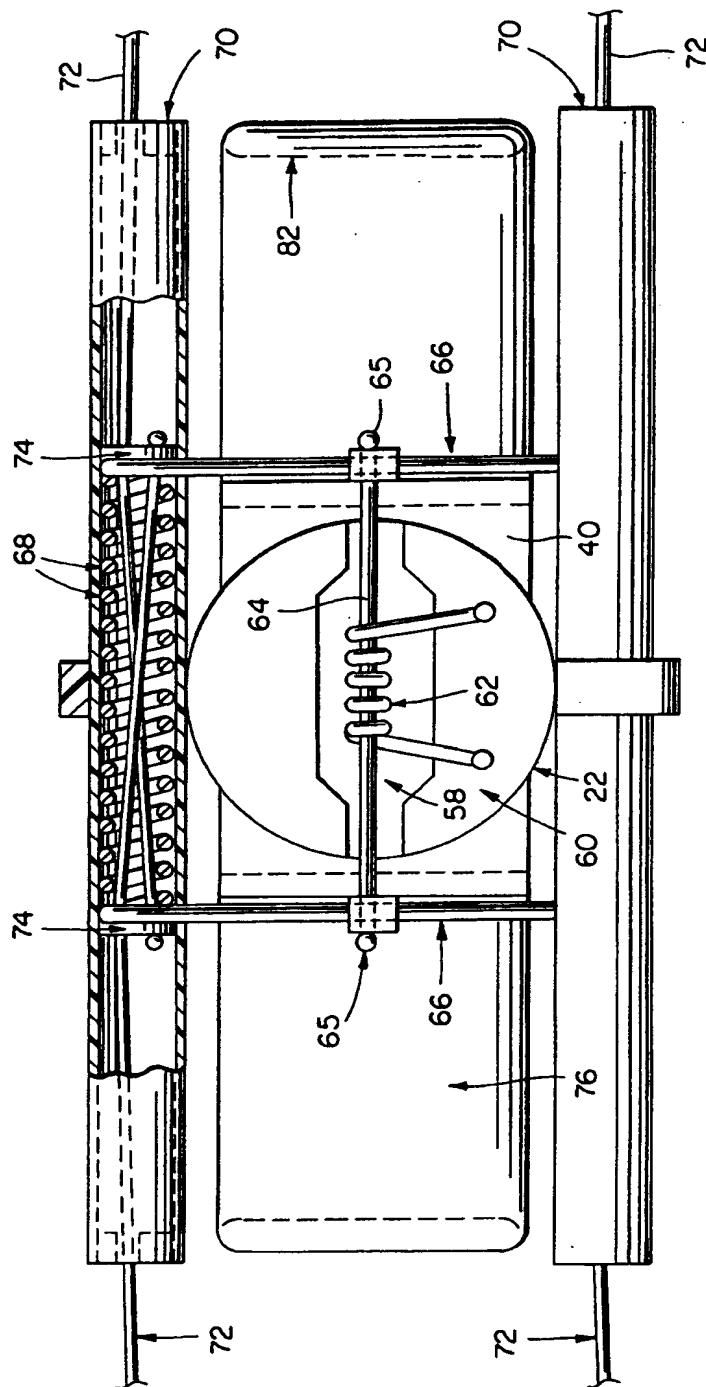


FIG. 3e



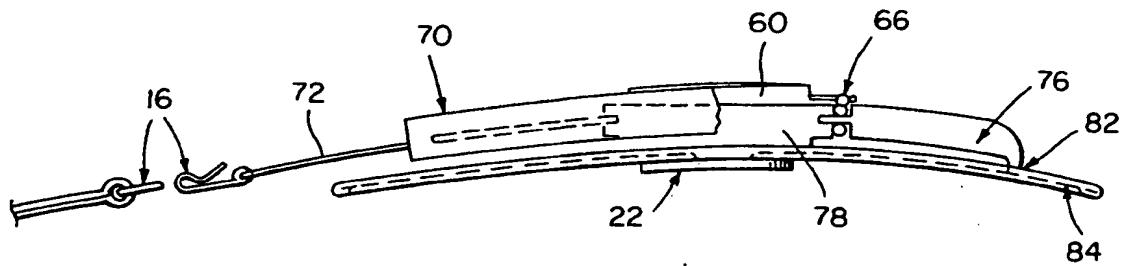


FIG. 3f

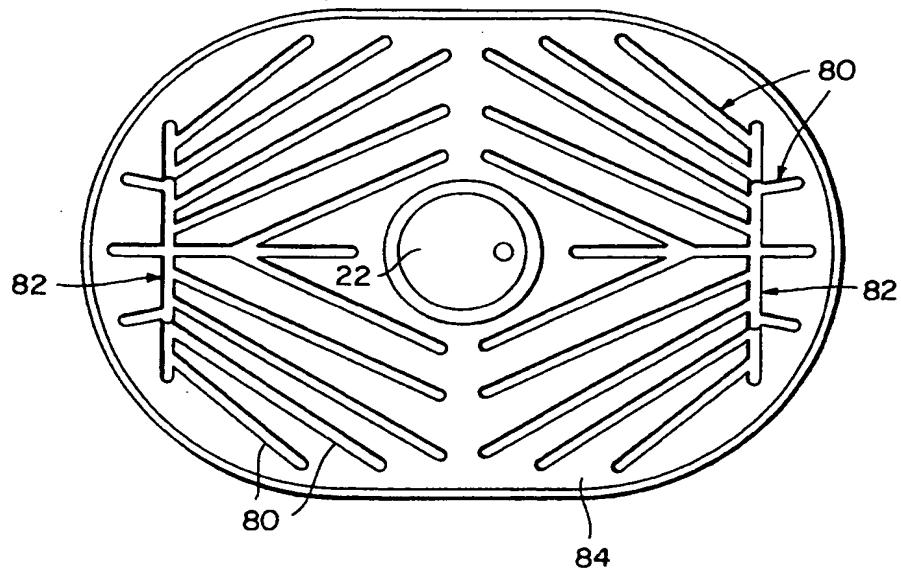


FIG. 3g

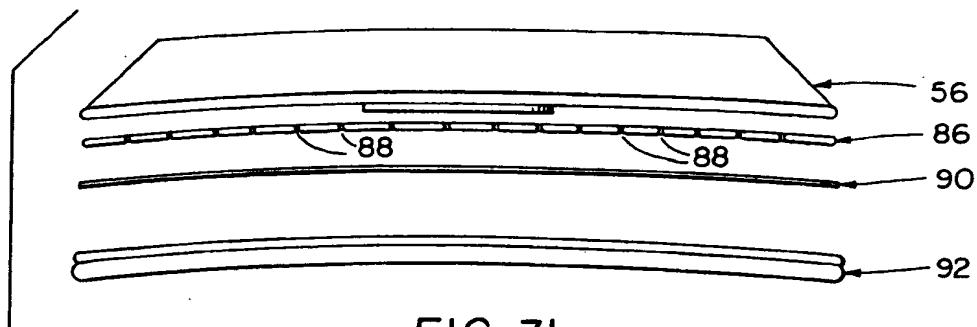


FIG. 3h

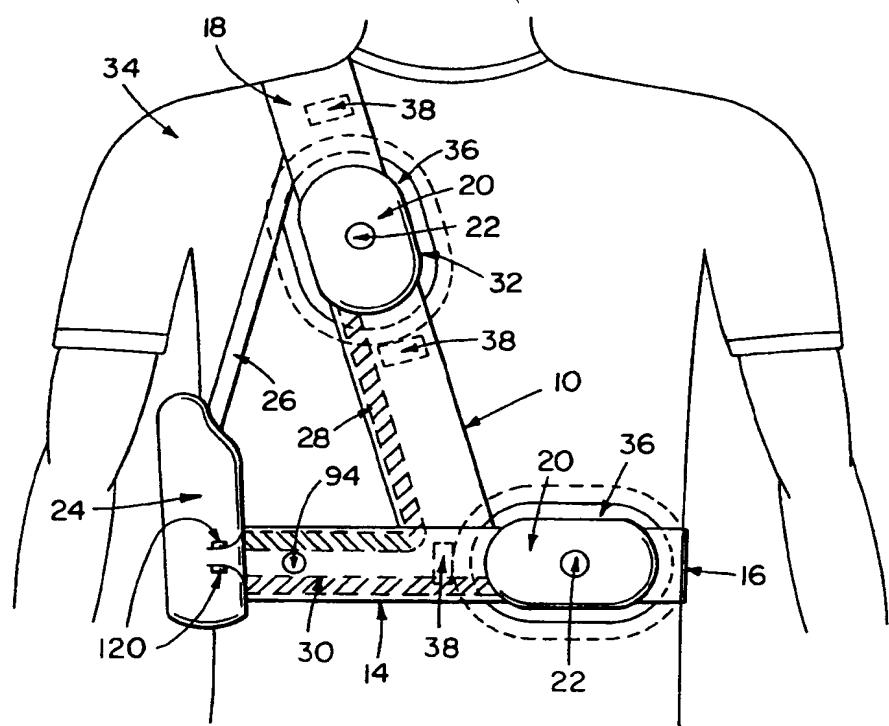


FIG. 4

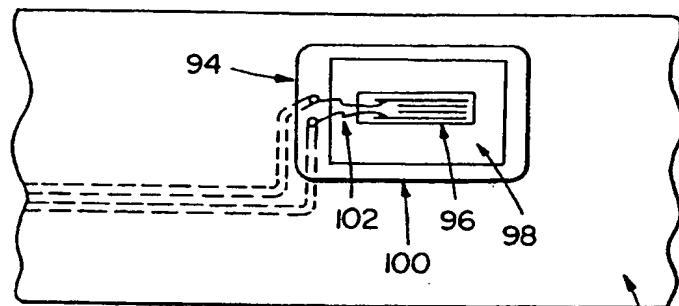


FIG. 5a

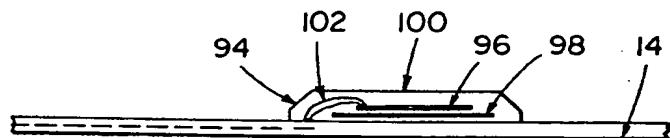


FIG. 5b

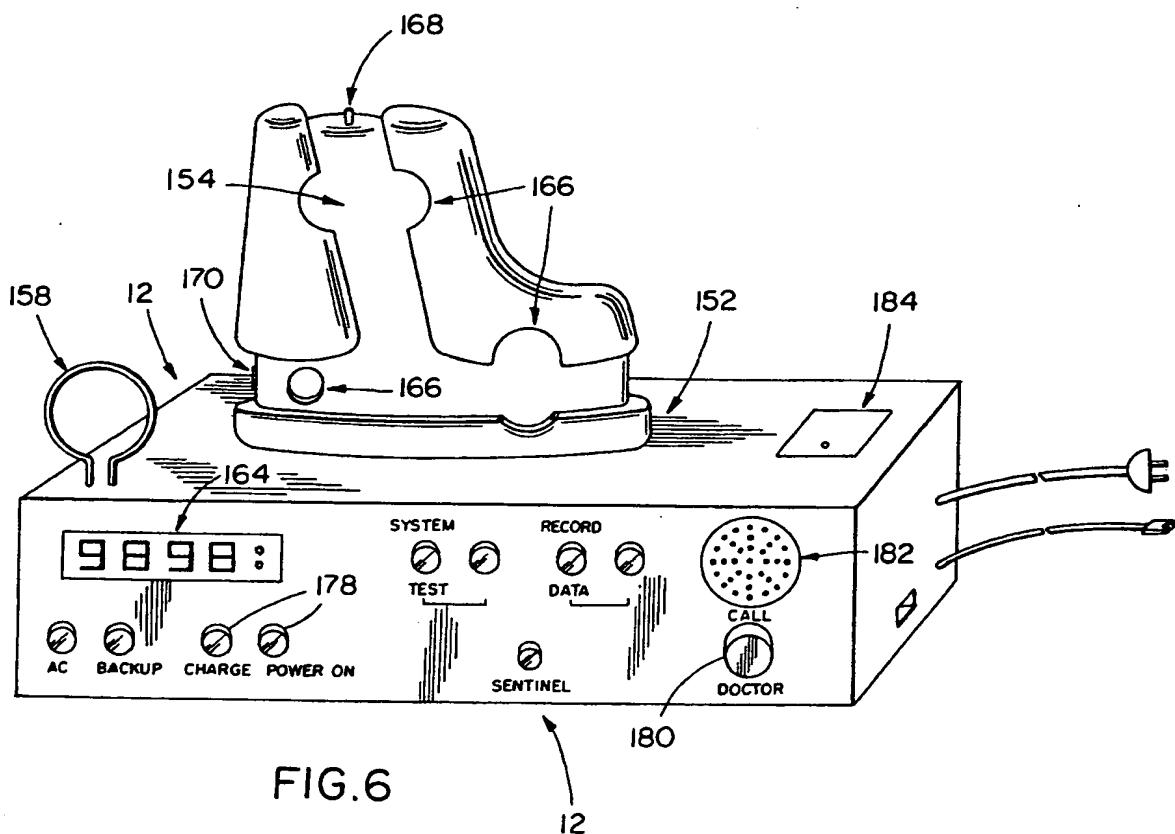


FIG. 6

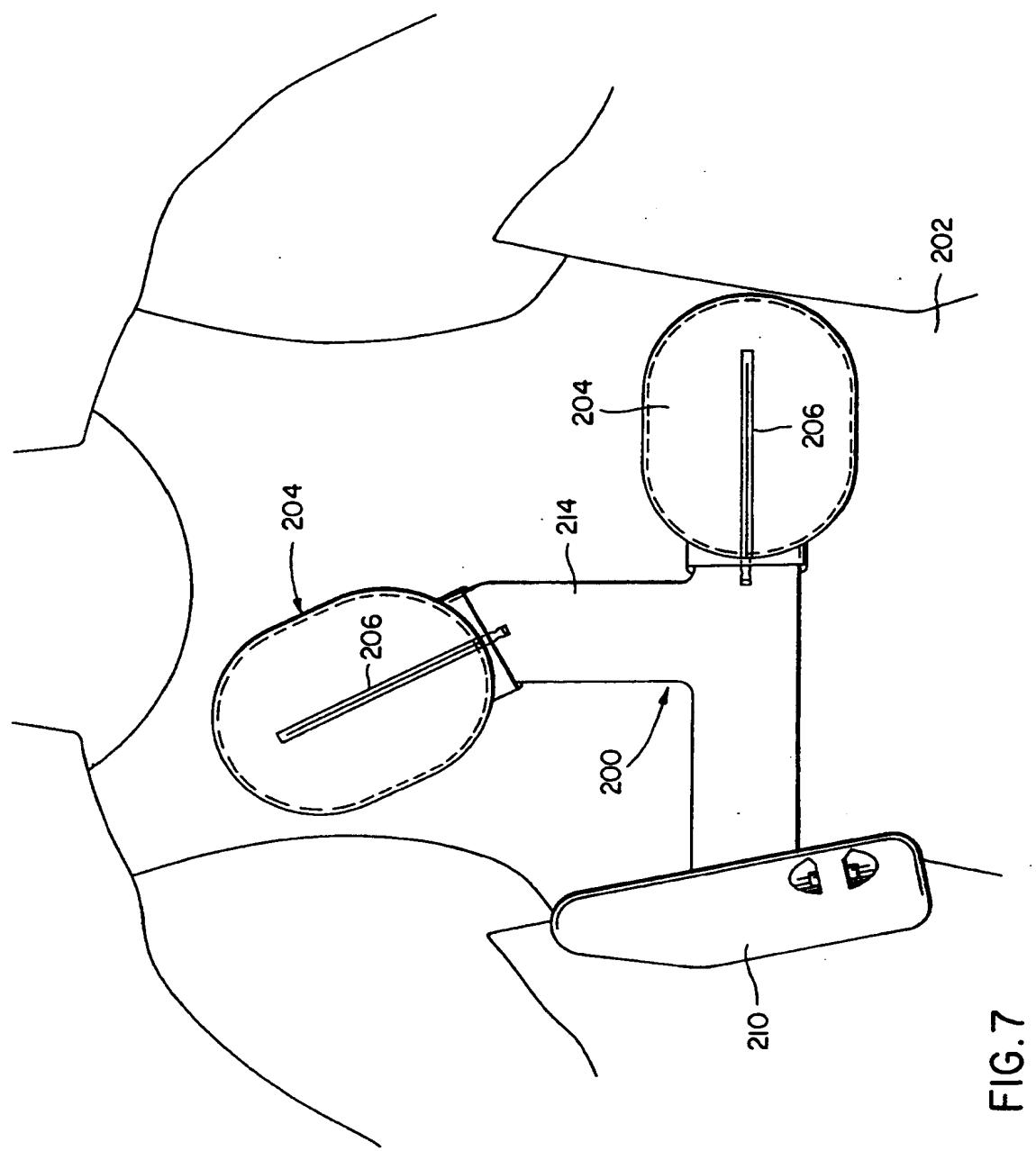


FIG. 7

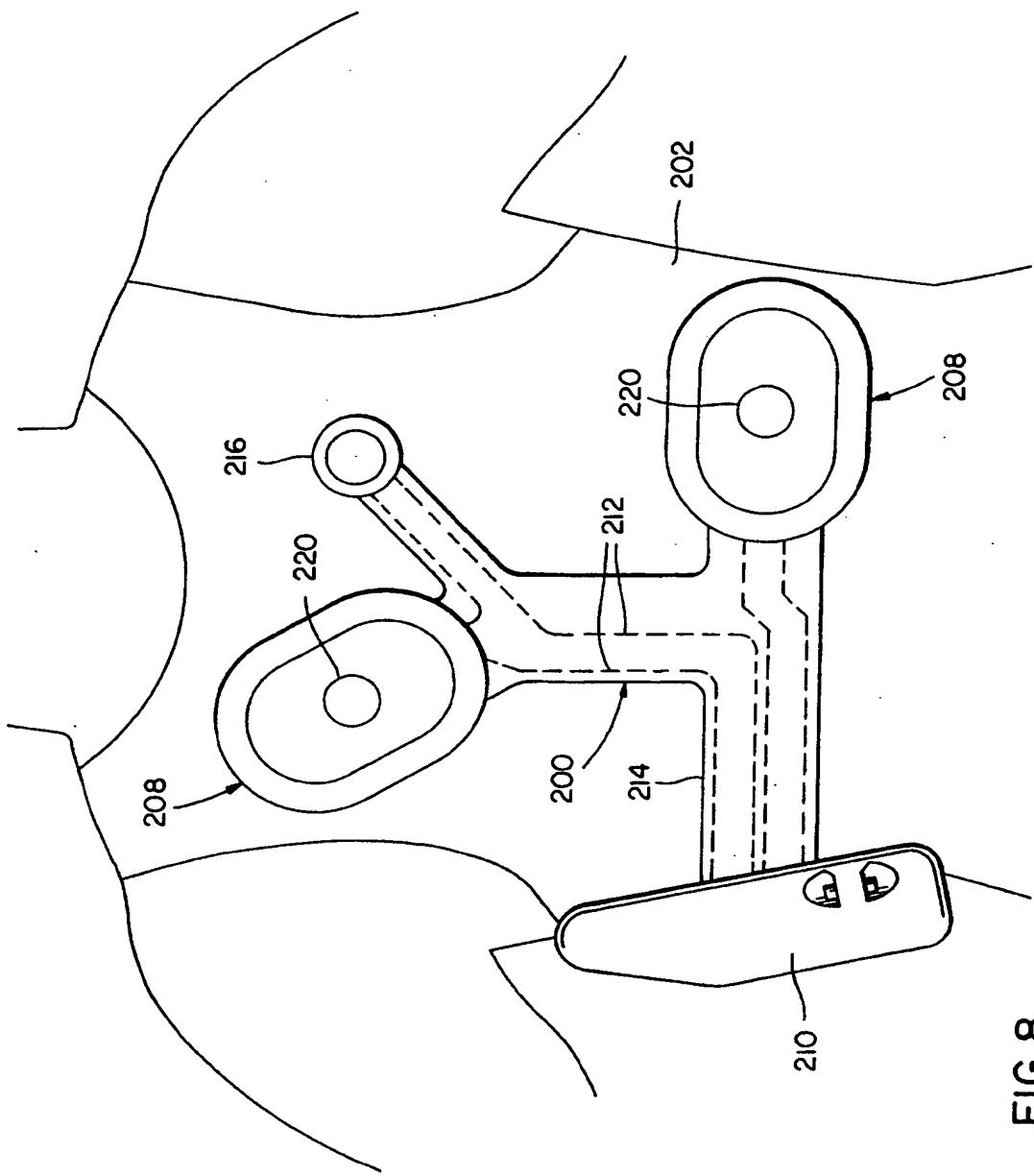


FIG. 8

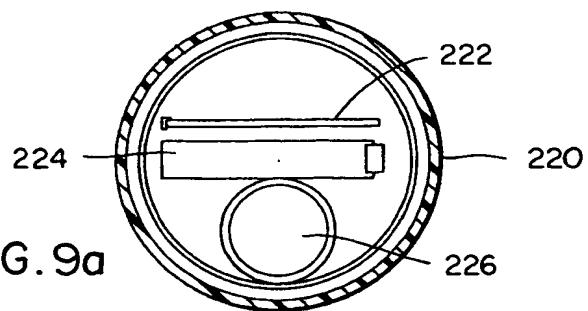


FIG. 9a

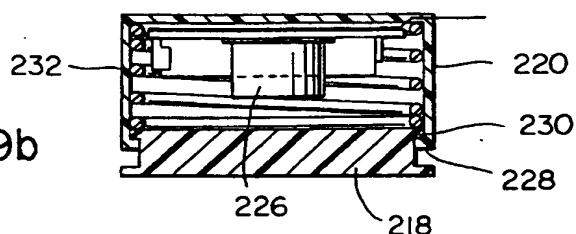


FIG. 9b

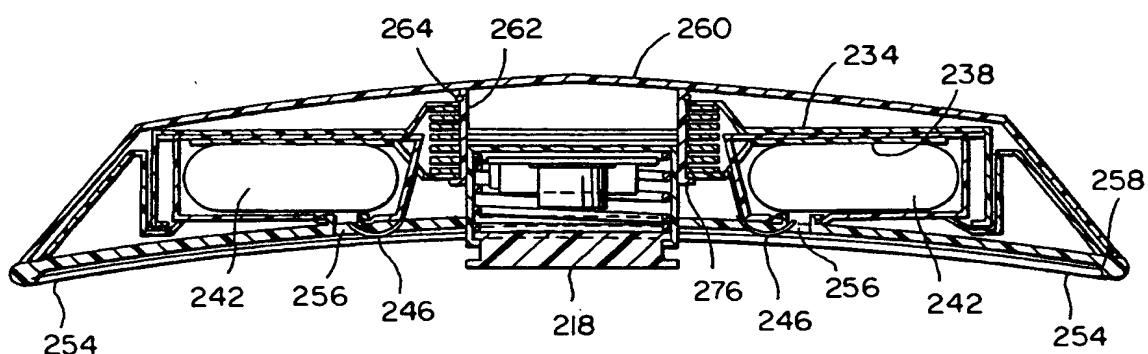


FIG. 10a

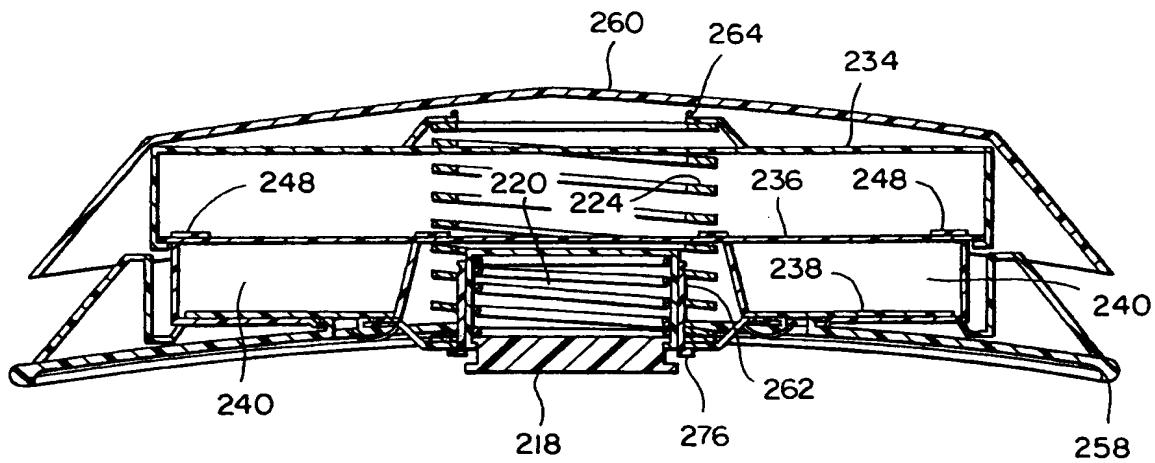


FIG. 10b

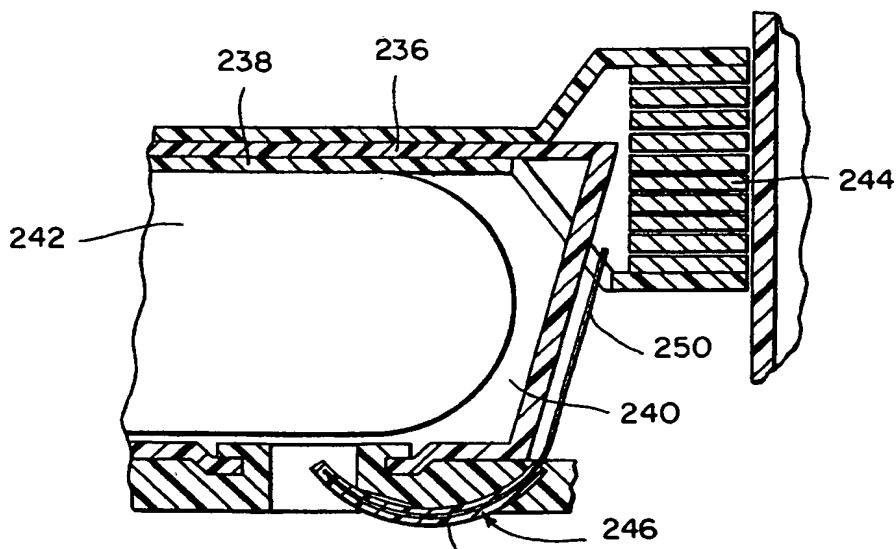


FIG. IOc

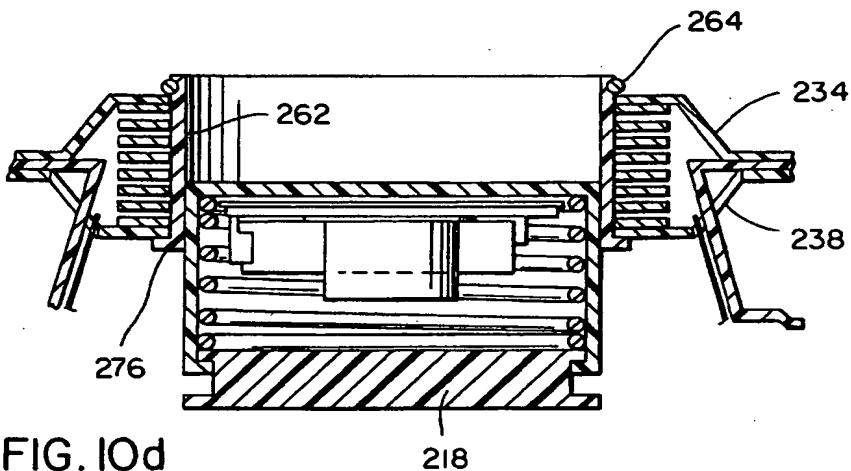


FIG. IOd

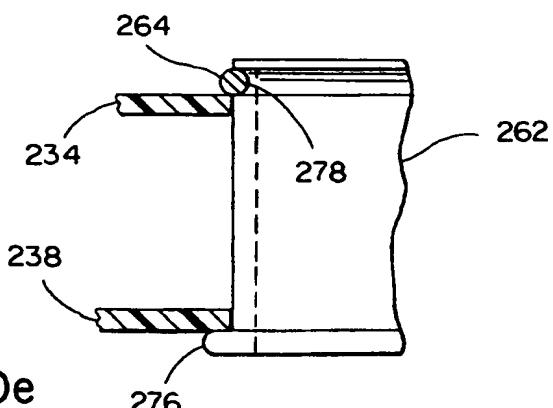


FIG. IOe

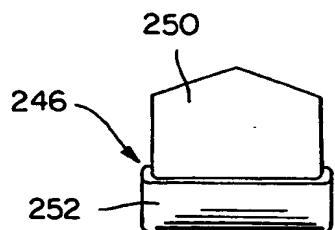


FIG. IIa

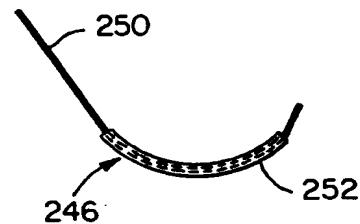


FIG. IIb

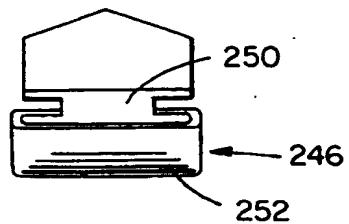


FIG. IIc

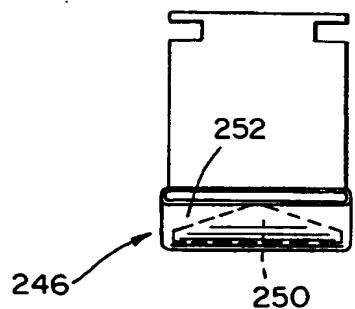


FIG. IId

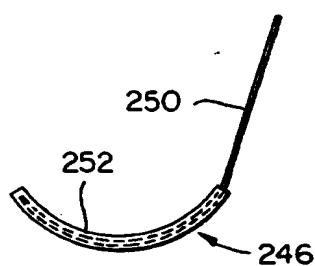


FIG. IIe

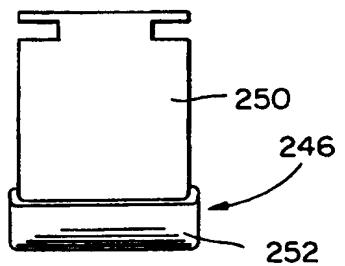


FIG. IIff

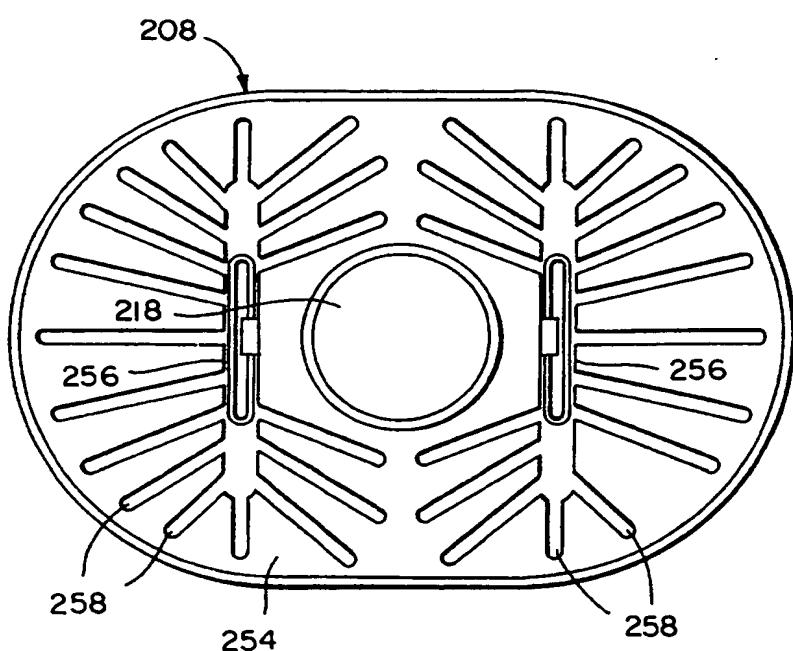


FIG. I2

FIG.13a

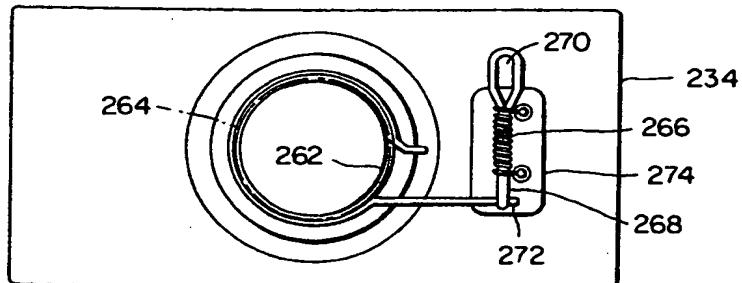


FIG.13b

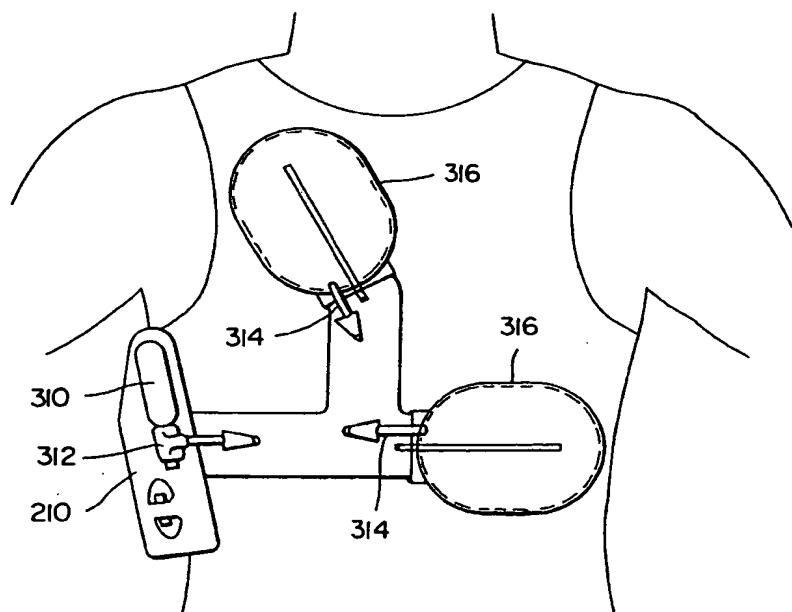
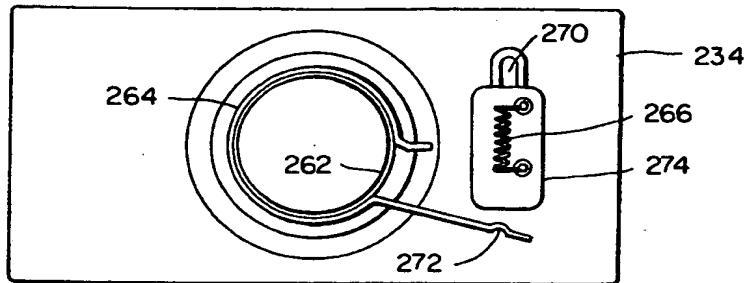


FIG.14

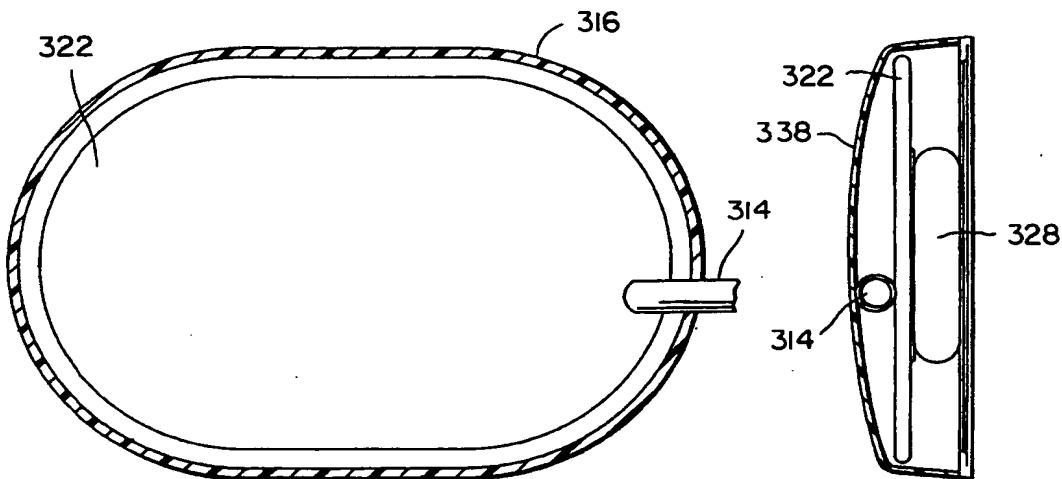


FIG.15a

FIG.15b

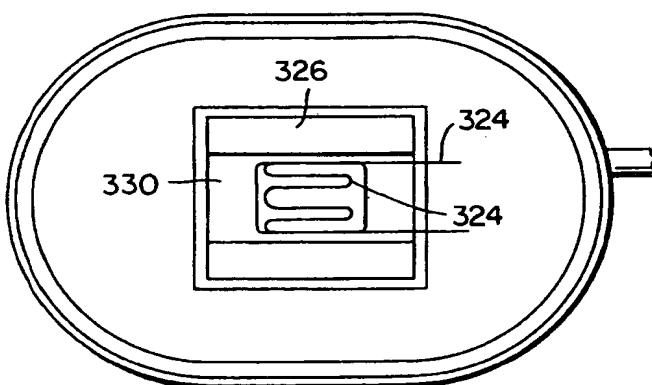


FIG.15c

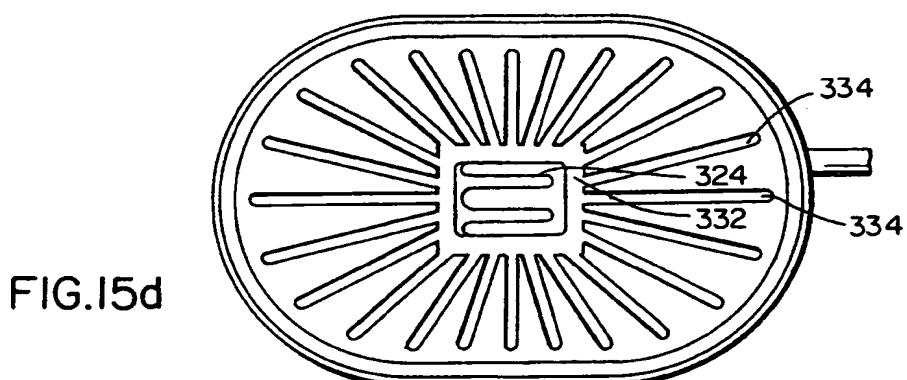


FIG.15d

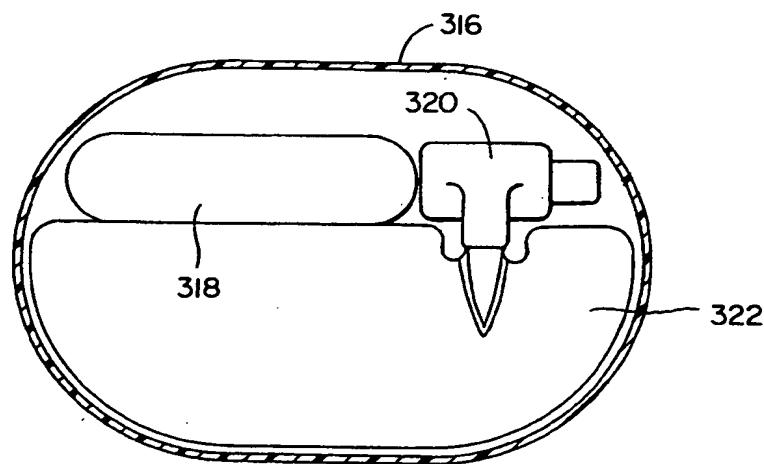


FIG. 16a

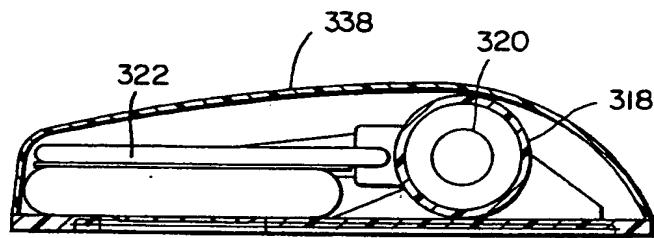


FIG. 16b

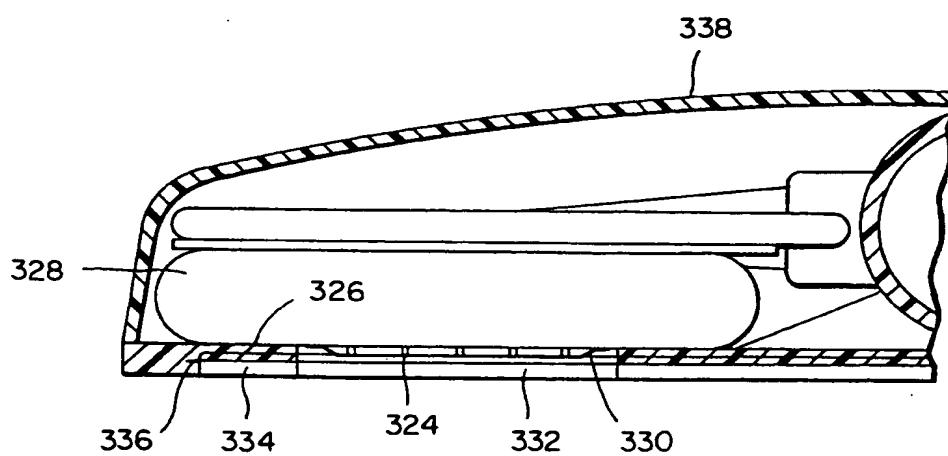


FIG. 16c

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